BIOMARKERS AND IMAGING

P001

The Swedish Early Psoriatic Arthritis (SWEPSA) registry 5-year follow-up: Slow radiographic progression with highest scores in male feet and patients with baseline x-ray abnormalities

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Objectives: The aim is to describe early X-ray findings in psoriatic arthritis (PsA) from the SwePsA registry using the Wassenberg score, evaluate progression of structural damage, analyze correlations to clinical disease parameters and identify predictors of progressive radiographic joint disease.

Methods: Out of 197 SwePsA patients followed for 5 years, 72 (38% of the women and 35% of the men) had radiographs at baseline and 5-year follow-up. Clinical data were collected according to the SwePsA protocol.

Results: Mean (SD) age of the 43 women and 29 men was 48.7 (15.0) and 46.4 (14.5) years. In the total SwePsA cohort women had higher disease activity (Theander *et al., Ann Rheum Dis* 2014; 73(2): 407–413), in this sub-cohort mean baseline DAS28/DAPSA were similar in women and men (3.94/22.27 and 3.73/21.63, ns). However, radiographic abnormalities were more pronounced in men. See Table for total score. Feet scores for women and men at baseline were 0.30 ± 0.74 versus 0.93 ± 1.69 ($P = 0.039$) and at 5 year 0.84 ± 2.13 versus 2.35 ± 3.92 ($P = 0.028$) respectively. Baseline and 5-year scores were highly correlated (for total scores: Spearman rho 0.752, $P = 0.000$). Baseline total score correlated with ESR (rho: 0.364, $P = 0.004$) and 5-year score with swollen joint count (rho 0.310, $P = 0.016$). Male gender and higher total baseline score were the only predictors of radiographic abnormalities after 5 years: OR (male/female): 4.42 (95% CI: 0.35–8.49) $P = 0.034$. Baseline total score: OR: 2.23 (1.80–2.65), $P = 0.000$. Only the baseline Wassenberg score was an independent predictor of radiographic progress. None of the 15 patients with the highest scores/progress had received TNF-blockers.

Discussion/Conclusions: Radiographic progression in early PsA is slow in general, very prevalent in male feet and predicted by baseline radiographic findings. Thus scoring of hand and feet X-rays at baseline cannot be substituted by clinical signs, especially not in men.

Disclosure of Interest: None to declare.

[P001] Table 1

		Baseline				
Gender	**Total score**	**Sign.**	**Erosion**	**Sign.**	**Proliferation**	**Sign.**
Men	3.05 ± 4.04	$P = 0.044$	1.17 ± 2.27	$P = 0.025$	1.79 ± 2.41	$P = 0.35$
Women	1.38 ± 2.44		0.30 ± 0.88		1.30 ± 1.99	
			5-year follow-up			
Men	7.79 ± 12.46	$P = 0.034$	3.41 ± 8.20	$P = 0.051$	4.62 ± 4.92	$P = 0.041$
Women	3.37 ± 4.85		0.86 ± 1.68		2.56 ± 3.49	

P002

Association between tumor necrosis factor inhibitor therapy and changes in C-reactive protein among patients with psoriasis, psoriatic arthritis, or rheumatoid arthritis

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Introduction: The use of tumor necrosis factor inhibitors (TNFi) for psoriasis is associated with a significant reduction in myocardial infarction (MI) incidence and risk,[1] and in cardiovascular mortality.[2]

Objective: To assess changes in C-reactive protein (CRP) for patients with PsO, PsA, or RA exposed to a TNFi with concomitant exposure to methotrexate (MTX) compared to patients exposed to methotrexate therapy with no TNFi.

Methods: This was a retrospective cohort study from data extracted from the electronic databases of the Kaiser Permanente Southern California (KPSC) Health Plan from January 1, 2002 to July 31, 2011. Patients had at least 3 ICD-9 diagnosis codes of PsO (696.1), PsA (696.0), or RA (714, 714.0, 714.1, 714.2, 714.4, 714.81) during the study period but prior to the index date. Among the underlying cohort of patients exposed to MTX, those who initiated a TNFi (adalimumab, etanercept, infliximab, or golimumab) anytime during the study period comprised the TNFi + MTX cohort. The study protocol was approved by the local institutional review board.

Results: There were 979 and 294 patients in the MTX and TNFi + MTX cohorts, respectively. The mean crude change was 1.1 mg/dl (SD = 19.84) for the MTX cohort and −9.2 mg/dl (SD = 26.64) for the TNFi + MTX cohort. In the main effects ANCOVA model, there was a significantly lower difference in the mean change of −5.18 mg/dl (95% CI: −8.24, −2.12) for the TNFi + MTX cohort compared to the MTX cohort after adjusting for baseline CRP, age, gender, type 2 diabetes, and inflammatory condition.

Conclusions: The use of TNF inhibitors with concomitant MTX was associated with a clinically and statistically significant decrease in CRP in patients with PsO, PsA, or RA.

Disclosure of Interest: J. Wu Grant/Research support from: AbbVie, Amgen, Coherus Biosciences, Eli Lilly, Janssen, Merck, Novartis, Pfizer, Regeneron, and Sandoz, Consultant of: AbbVie, Amgen, Celgene, DUSA Pharmaceuticals, Eli Lilly, and Pfizer; C. Rowan: None to declare; J. Bebchuk: None to declare; M. Anthony Shareholder of: Dr Anthony owns stock of Amgen, Employee of: Dr Anthony was employed by Amgen during the study.

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P003

Assessments of neutrophil to lymphocyte ratio and platelet to lymphocyte ratio in Korean patients with psoriasis vulgaris and psoriatic arthritis

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Introduction: There are no simple and clinically useful biomarkers for both psoriasis and PsA patients yet. Recently, the neutrophil to lymphocyte ratio (NLR) and platelet to lymphocyte ratio (PLR) have been recognized as markers for inflammatory markers of cardiac and noncardiac disease and indicators for poor prognosis in various cancers.

Objectives: To assess neutrophil to lymphocyte ratio (NLR) and platelet to lymphocyte ratio (PLR) as inflammatory markers in patients with psoriasis and psoriatic arthritis (PsA).

Methods: This was a retrospective cross-sectional study. A hundred and eleven psoriasis patients and 25 PsA patients were compared to 94 healthy controls. Demographic, clinical and laboratory information were collected and analyzed. NLR and PLR were calculated. White blood cell (WBC), neutrophils, eosinophils and NLR were increased in psoriasis patients compared to controls.

Results: WBC, neutrophils, NLR, monocytes, platelets and PLR were increased in PsA patients compared to both controls and psoriasis patients. ESR and CRP were significantly higher in PsA patients compared to psoriasis patients. Among psoriasis patients, PASI score correlated positively with platelets, NLR and PLR. These parameters were all significantly higher in moderate to severe psoriasis patients (PASI $\geqslant$ 10) compared to mild patients (PASI $<$ 10). Elevated platelets, NLR and PLR were statistically significant predictors of the increased PASI scores in multivariate analysis. NLR, PLR and ESR were statistically significant predictors for the presense of PsA in psoriasis patients. NLR was the strongest predictor (OR 3.351, $P = 0.005$).

Conclusions: In conclusion, elevated NLR and PLR were significantly associated with psoriasis and PsA. Both NLR and PLR can be used as one of the inflammatory markers in patients in psoriasis and PsA.

Disclosure of Interest: None to declare.

P004

Ultrasound enthesitis in primary care psoriasis patients with musculoskeletal complaints

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Introduction: Psoriasis patients with enthesitis can classify as psoriatic arthritis since the introduction of the CASPAR classification criteria in 2006. However, clinical assessment of the entheses could be challenging. Therefore, we need a better way to identify the inflammatory component of entheseal involvement in psoriasis. To detect these inflammatory components at the entheses, an ultrasound (US) examination can be used to identify inflammatory disease at the entheses.

Objectives: Our aims were to determine the prevalence of US abnormalities among psoriasis patients in primary care and to determine the concordance of clinical and US information at individual entheseal sites.

Methods: Adult primary care patients with psoriasis were invited. Patients who reported pain in joints, entheses or the lower back were clinically evaluated. If a painful enthesis on the LEI/MASES or if arthritis was present, US examination of the entheses was performed. Seven entheses were evaluated according to the Madrid Sonographic Enthesis Index (MASEI) scoring system. Structural US changes were calcifications, increased thickness, irregular fibre structure and erosions. Enthesitis was defined as US inflammation (ie positive power Doppler (PD) signal or a thickened enthesis of the plantar fascia) with one clinical feature at the same enthesis (ie tender LEI/MASES enthesis; reported pain in the history; self-reported pain in the questionnaires).

Results: In total, 111 patients were assessed both by physical examination and by US. In 106 (95%) patients we detected US abnormalities. In 56 (50%) patients we found structural changes without indication for inflammatory disease. In 50 (45%) patients we found US abnormalities indicating inflammatory disease at the enthesis (positive PD: $n = 35$; thickened plantar fascia: $n = 15$). When we combined US data with clinical information, 36% of US inflammatory disease were confirmed.

Conclusions: We found US abnormalities in 95% of the primary care psoriasis patients with musculoskeletal complaints. In 45% of primary care psoriasis patients we observed US inflammatory disease, which was confirmed in 36% of the patients by clinical information.

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CLINICAL PHENOTYPES

P005

Clinical features and course of generalized pustular psoriasis in Korea

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Introduction: The clinical course of generalized pustular psoriasis (GPP) is variable and unpredictable. Sufficient data on the clinical course of the disease has not been reported due to its rarity.

Objectives & Methods: To investigate the clinical features and course of GPP according to its subtypes, medical records of patients diagnosed with GPP from 2002 to 2012 at two tertiary hospitals were reviewed. The data included patient demographics, associated symptoms, aggravating factors, patterns of relapse, and prognosis.

Results: Thirty-three patients with GPP were included in our study, with a mean age of 45.6 years and a male:female ratio of 1:1.2. Patients were categorized based on the following subtypes: acute GPP, 21 (63.6%); GPP of pregnancy, 2 (6.1%); juvenile GPP, 3 (9.1%); and annular GPP, 7 (21.2%). In the acute GPP population, skin lesions cleared within 2 months in 11 (73.3%) of patients, and 6 (40.0%) of these patients had no relapse. Severe complications, abortion or death, were observed in two patients (100.0%) with GPP of pregnancy. Nineteen (76.0%) of GPP patients experienced persistence or relapse of skin lesions. The patterns of skin lesions upon relapse included plaques in 6 patients (31.6%), pustules in 8 patients (42.1%), and plaques and pustules in 5 patients (26.3%). Among acute GPP patients, 16.7% of patients with no relapse had a history of plaque psoriasis.

Conclusions: Our study presents the detailed clinical course of GPP by subtype in Korean patients.

Disclosure of Interest: None to declare.

COMORBIDITIES

P007

Psoriasis may not be a significant risk factor for ischemic cardiovascular diseases: results from a matched nationwide cohort study

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Introduction: The complex associations among psoriasis, systemic treatment and cardiovascular diseases continue to be debated.

Objectives: To determine the independent role of psoriasis in the development of cardiovascular diseases and the effects of disease severity and systemic anti-psoriatic treatments.

Methods: A nationwide cohort study from Taiwan's National Health Insurance Research Database between 1997 and 2011. We identified three age-, gender- and comorbidities-matched study groups, consisting of 26892 patients (severe psoriasis), 26892 patients (mild psoriasis) and 107568 patients (reference cohort). The risks of ischemic heart disease and stroke were compared among the three groups. Cumulative incidences and hazard ratios were calculated after adjusting for competing mortality. Additional adjustments were made for presence of psoriatic arthritis; anti-inflammatory drugs; number of hospital visits and Charlson's comorbidity index.

Results: The risks of ischemic heart disease and stroke were comparable among the three cohorts, with 12-year adjusted cumulative incidences of 15.83% (95% CI 15.26–16.39), 15.31% (95% CI 14.74–15.88) and 15.44% (95% CI 15.14–15.74), respectively. Multivariate stratified analyses indicated comparable risks for ischemic heart disease and stroke for mild and severe psoriasis in terms of matched reference subjects in almost every subset of patients. Subjects with severe disease taking biologics, methotrexate or retinoid had lower incidence rates of ischemic heart disease and stroke than those not taking these drugs. No significant differences of risk were observed among patients taking each of these three drugs.

Conclusions: Psoriasis has comparable risks for ischemic heart disease and stroke in terms of cardiovascular risk factor-matched reference subjects. Use of biologics may be associated with lower risks in severe psoriasis.

Disclosure of Interest: Y.-J. Chen Consultant of: Celgene Pty LtD.; C.-Y. Wu: None to declare; Y.-T. Chang: None to declare.

P009

A study of awareness and screening behavior of cardiovascular risk factors in patients with psoriasis and dermatologists

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Introduction: A number of studies have suggested that an increased frequency of cardiovascular (CV) diseases in patients with psoriasis.

Objectives: In this study, we assessed the awareness among psoriasis patients and dermatologists in private primary clinics about the increased CV risk linked to psoriasis, and examined the screening behaviors of dermatologists for CV risk factors in psoriasis patients.

Methods: We distributed the questionnaires to dermatologists in primary clinics and psoriasis patients about their awareness of the increased CV risk factors in psoriasis patients.

Results: One hundred and four patients and 50 dermatologists were included; 64.4% of patients and 92% of dermatologists answered that they knew that the risk of CV diseases increased in psoriasis patients. However, far fewer dermatologists than expected followed the screening guidelines for CV risk factors. We found that duration ($P<0.0001$) and severity ($P<0.0001$) of psoriasis were related to patient's awareness. A significant correlation between dermatologist's awareness and the number of psoriasis patients they cared for each month was also observed ($P<0.024$).

Conclusions: This study may help promote the idea that psoriasis patients require education about increased CV risk factors and that dermatologists require further education about screening practices to detect CV risk in psoriasis patients.

Disclosure of Interest: None to declare.

P006

Frequency and prevalence of flares in psoriasis: results of the Adelphi Real World Psoriasis Disease Specific Programme in the United States

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Introduction: Plaque psoriasis is a chronic disease with periods of exacerbation (flares) and remission.

Objectives: To report the frequency and prevalence of flares in patients (pts) with moderate to severe psoriasis in the US.

Methods: This was a retrospective, cross-sectional analysis of survey data of pts with psoriasis treated by a dermatologist from Jan to Mar 2013 in the Adelphi Real World Psoriasis Disease Specific Programme. Data included pt demographics, clinical information and medication use. Differences are described between flaring and non-flaring pts using Wilcoxon rank sum and Fisher's exact tests. Flaring was defined as pts with current disease activity, with worsening/unstable disease progression, and included pts in remission $\leqslant$12 weeks according to indicators of current disease activity.

Results: Of the 525 pts available for analysis, 142 (27.0%) were categorised as currently flaring. Flaring pts who experienced an episode had a mean of 2.1 physician-defined episodes/year, with mean length of 30.1 days. Females had more flares than males (54.6% versus 45.4% with flares; $P=0.0056$); age and body mass index were not significant factors. Time since diagnosis was shorter for flaring versus non-flaring pts (median: 20.7 versus 46.6 months; $P<0.0001$). Current disease severity was greater in flaring pts: physician-rated disease severity, 'severe' 26.1% versus 1.6%, for flaring versus non-flaring, respectively ($P<0.0001$); median Psoriasis Area and Severity Index 12.0 versus 8.0 ($P=0.0002$). Anxiety ($P=0.0139$) and renal impairment ($P=0.0374$) were significantly associated with increased risk of flaring. A greater proportion of flaring pts (versus non-flaring) was not currently treated with biologic therapies (71.0% versus 56.3%; $P=0.0031$).

Conclusions: To our knowledge, this is the first characterisation of flaring in pts with moderate to severe psoriasis. Over a quarter of pts were currently affected by flaring. Flaring was associated with significantly worse disease severity and was more common in pts with a shorter time since diagnosis, possibly indicating that the most appropriate treatment regimen for disease management has not yet been determined.

Disclosure of Interest: C. Mamolo Shareholder of: Pfizer Inc, Employee of: Pfizer Inc; J. Lucas Employee of: Adelphi Real World; R. Wood Employee of: Adelphi Real World; J. C. Cappelleri Shareholder of: Pfizer Inc, Employee of: Pfizer Inc; J. Piercy Employee of: Adelphi Real World; L. Mallbris Shareholder of: Pfizer Inc, Employee of: Pfizer Inc at the time of data analysis and abstract development; M.-A. Hsu Shareholder of: Pfizer Inc, Employee of: Pfizer Inc.

P008

The difference of cardiovascular risk factor between mild psoriasis patients and moderate to severe psoriasis patients group

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Introduction: Psoriasis is a chronic inflammatory skin disease that is associated with an increased cardiovascular risk profile. The relationship between PASI and cardiovascular risk factor has not been evaluated in Korean psoriasis patients yet.

Objectives: We aimed to evaluate the relationship between PASI and cardiovascular risk factors in Korean patients.

Methods: Physical examination, serum lipid profile analysis, and the medical history of the psoriasis patients were reviewed. The severity of psoriasis was assessed using Psoriasis Area Severity Index (PASI) scores: mild, <10; moderate to severe, $>=10$. A total of 96 patients with plaque type psoriasis were included.

Results: Significant differences of prevalence of cardiovascular risk factor and the level of lipid profile according to the severity of the psoriasis were not discovered except triglyceride level.

Conclusions: Our results suggest that there is no close correlation between the severity of psoriasis and cardiovascular risk factor in Korean psoriasis patients.

Disclosure of Interest: None to declare.

P010

Arterial stiffness and carotid intima–media thickness in Asian patients with psoriasis

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Introduction: The risk of cardiovascular events is reportedly elevated for psoriasis patients. Evaluation of the beta stiffness index (BSI) and carotid intima–media thickness (IMT) are noninvasive methods of assessing arterial stiffness and subclinical atherosclerosis.

Objective: To compare the carotid arterial stiffness and IMT of Asian psoriatic patients and healthy controls, using high-resolution ultrasonography, to analyze if psoriasis is an independent risk factor for the differences in values, and to determine their correlation with clinical characteristics among psoriasis patients.

Methods: Fifty-four psoriatic patients and 60 age- and gender-matched healthy volunteers were enrolled. The BSI and IMT of the common carotid artery were assessed using a high-resolution, B-mode ultrasonographic echo-tracking system.

Results: Psoriasis patients exhibited a significantly higher BSI compared with control subjects ($P<0.001$). The IMT tended to be higher in patients with psoriasis, but was not statistically significant ($P=0.076$). There was no significant difference in the presence of carotid plaques between groups. BSI was positively correlated with age, systolic blood pressure, disease severity defined according to the history of systemic treatment, and traditional cardiovascular disease (CVD) risk factors. Psoriasis was independently correlated with BSI.

Conclusions: This study showed that psoriasis was independently associated with arterial stiffness. Increased arterial stiffness in patients with psoriasis suggests that the risk of cardiovascular disease is elevated in relatively non-obese Asian psoriatic patients. Arterial stiffness represents a functional vascular change, and allows for earlier detection of CVD than IMT, which represents a structural vascular change. Using BSI to assess CVD may allow patients to benefit from more timely intervention.

Disclosure of Interest: None to declare.

P011

Decreased plasma Brain-Derived Neurotrophic Factor (BDNF) levels in psoriasis: a case-control study

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Introduction: Brain-derived neutrophic factor (BDNF) is a molecule associated with neuroplasticity and synaptic strengthening, being decreased in mental disorders and other conditions associated with chronic stress. Nonetheless, BDNF has not yet been investigated in psoriasis, a chronic inflammatory skin disease that exacerbates with stress and is associated with mental illness.

Objectives: To determine BDNF plasma levels in patients with psoriasis and healthy volunteers.

Methods: Case-control study. We enrolled adult patients ($n=94$) with psoriasis for at least one year, which were matched by age and gender with healthy volunteers ($n=307$) from the Brazilian Longitudinal Study of Adult Health (Elsa-Brasil). Participants presented no history of mental disorders or coronary artery disease. BDNF plasma levels were determined using the Promega ELISA kit. We performed a general linear model in which age, gender, systolic blood pressure, serum glucose, HDLc, LDLc, triglycerides, smoking status and body mass index were input to compare BDNF levels in psoriasis versus controls.

Results: After adjustment for clinical and demographic variables, BDNF plasma levels were significantly decreased ($P=0{,}01$) in psoriasis (estimated marginal means of 3922 pg/ml; 95% CI 2660–5135) versus controls (5788 pg/ml; 95% CI 5185–6442). Similar levels were found in mild versus severe psoriasis.

Conclusion: Our findings support the "brain-skin" connection in psoriasis as BDNF, a critical neurotrophin associated with neuroplasticity, is decreased in psoriasis. Further studies should investigate whether BDNF increases after treatment and is associated with disease severity.

Disclosure of Interest: None to declare.

P012

The impact of depression on the risk of myocardial infarction, stroke, and cardiovascular death in patients with psoriasis: a Danish nationwide study

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Introduction: Psoriasis is a chronic inflammatory disease associated with depression, myocardial infarction (MI), and stroke. Patients with depression have an increased cardiovascular risk, but the link between psoriasis, depression, and cardiovascular disease is unclear.

Objectives: To investigate the impact of depression on the risk of MI, stroke, and cardiovascular death in patients with psoriasis.

Methods: All patients with psoriasis and incident depression aged ⩾ 18 years from 1997 to 2011 were identified as cases, and matched with up to four patients with psoriasis without depression (controls). Information (eg age, gender, socio-economic status, medication, and comorbidity) was linked at individual-level through administrative registries. Information on comorbidity and medication was continuously updated throughout the study period. Depression was modeled as a time-dependent variable to estimate the effects of acute and chronic depression, and remission from depression, respectively. The primary endpoints were a diagnosis of MI, stroke or cardiovascular death, respectively. Incidence rates were calculated and incidence rate ratios (IRRs) adjusted for age, gender, socio-economic status, medication, and comorbidity were estimated by Poisson regression models.

Results: The cohort comprised 29,406 Danish patients with psoriasis, including 6,244 patients with incident depression. Risk of MI (IRR 1.57, 95% confidence interval [CI] 1.07–2.29), stroke (IRR 1.95, 95% CI 1.43–2.66), and cardiovascular death (IRR 2.24, 95% CI 1.53–3.26), was significantly increased during stages of acute depression, and the risk of stroke (IRR 1.51, 95% CI 1.19–1.90) was significantly increased in chronic depression. During remission from depression, only the risk of stroke continued to be increased, compared with patients who never experienced depression.

Conclusions: In psoriasis patients, depression is associated with an increased risk of MI, stroke, and cardiovascular death, especially during acute depression. Focus on symptoms of depression in patients with psoriasis may be relevant to potentially reduce their risk of cardiovascular morbidity and mortality.

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P013

Skin-mediated promotion of thrombosis is abrogated following IL-23/IL-17 inhibition or IL-6 deletion in mouse models of psoriasis

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Introduction: Psoriasis patients are at increased risk of dying of heart attack and stroke and have elevated S100A8/9 levels, which are predictive of poor CVD event outcomes. S100A9$^{-/-}$ mice develop less atherosclerosis and are protected against thrombosis. KC-Tie2 mice develop a psoriasis-like skin phenotype, have elevated skin and serum S100A9 and are pro-thrombotic.

Objectives: We hypothesized that genetic deletion of S100A9 in KC-Tie2 mice would improve skin disease, decrease systemic inflammation and be thrombo-protective.

Methods: KC-Tie2 and S100A9$^{-/-}$ mice were mated and skin inflammation, circulating pro-inflammatory cells and thrombosis outcomes were examined.

Results: Thrombosis was similar between KC-Tie2 × S100A9$^{-/-}$ and KC-Tie2 mice ($n=14$–20/grp; $P=0.9$), perhaps due to persistent skin inflammation, elevated pro-inflammatory cytokines including IL-6, IL-17A, IL-12/23 ($n=9$–12; ∼5–6-fold; $P<0.05$) and sustained circulating Ly6C^{hi} monocytes ($n=3$–7; ∼4-fold; $P<0.01$). To explore the contributions of these cytokines in promoting thrombosis, we backcrossed KC-Tie2 with IL-6$^{-/-}$ mice or treated KC-Tie2 mice with clinically validated cytokine function blocking antibodies targeting IL-17A, IL-17RA, IL-12p40, and IL23p19 ($n=7$–14/grp). Thrombosis returned to control mouse levels in KC-Tie2 × IL-6$^{-/-}$ mice ($n=14$–20) and was significantly improved in KC-Tie2 mice treated with each of the cytokine function blocking antibodies versus IgG controls ($P<0.05$ each). Improvement in skin inflammation was only observed in KC-Tie2 mice treated with antibodies, not KC-Tie2 × IL-6$^{-/-}$ animals, consistent with clinical reports of skin improvement following IL-23/IL17 pathway inhibition, but not IL-6. We hypothesized that circulating monocytes contribute to atherothrombosis, however IL-6 deletion failed to decrease this cell population, whereas functional inhibition of IL-23/IL-17 pathway did, despite thrombosis improving in all groups.

Conclusions: These data reveal a critical role for skin-derived IL-6 and the IL-23/IL-17 pathways in promoting thrombosis related to psoriasiform inflammation and suggest that thrombotic events occur independently of elevated monocytes in KC-Tie2 mice.

Disclosure of Interest: None to declare.

P014

Prevalence and determinants of psychiatric disorders in patients with psoriasis

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Introduction: Psoriasis is a common skin disorder and is associated with impairments in quality of life and psychological distress.

Objectives: We investigated the prevalence and determinants of psychiatric morbidity in form of psychiatric disorders among patients with chronic plaque psoriasis approaching a dermatology service in our institute.

Methods: A two-stage cross-sectional assessment using a standardized self-rated diagnostic instrument (Patient Health Questionnaire), severity of psoriasis and a quality of life (QOL) assessment followed by a clinician-administered diagnostic instrument (Mini International Neuropsychiatric Interview) was conducted on 104 consenting consecutive patients from January to November 2013.

Results: The prevalence of any psychiatric disorder was 19.23% with the self-rated instrument and 45.19% with the clinician rated instrument. Depressive disorders were the most common group of diagnoses. Impairment in quality of life (QOL) was found to be predictive of any psychiatric disorder and depressive disorders.

Conclusions: Our findings suggest a need for effective screening for psychiatric disorders in psoriasis, a greater sensitivity to the association of QOL and psychiatric morbidity and the necessity of inputs from mental health professionals towards ensuring better outcomes for patients.

Disclosure of Interest: None to declare.

P015

Clinical outcome of a novel promising anti CD-6 biologic Itolizumab, in 7 patients with psoriasis and comorbid conditions

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Introduction: Psoriasis is universal in occurrence, its prevalence in different population group varies from 0.1 to 11.8%.[1] The root cause is unknown but with a strong genetic basis, T-cell mediated cytokines and keratinocytes forming an integral part of the cutaneous immune response, many biologic agents have shown promising results in management of psoriasis. Itolizumab is a novel anti CD-6 humanized monoclonal antibody which works upstream by inhibiting the co-stimulation of T cells, lowering release of signature cytokines of Th1 & Th 17 cells.[2]

Objectives: The aim of this study was to ascertain clinical efficacy, long term remission, safety , immunogenicity and improvement in DLQI of the patients with psoriasis and comorbid conditions.

Method: Study was designed on humans, 52 weeks study with follow ups, number of subjects included were 7 stratified by baseline PASI, DLQI and comorbid conditions. All patients were only on topical modality of treatment for 2 months before inclusion into the study. A dose of Itolizumab 1.6 mg/kg body weight was given by intravenous route for 10 infusions, 6 infusions at 15 days intervals and rest 4 at monthly intervals to maintain the desired serum level of C min >10 ugm/ml. All the patients were intolerant/non-responders to conventional immunosuppressants/immunomodulators.

Result: A statistically significant improvement in PASI at baseline to PASI at the 10th infusion was achieved in all patients and similar results were obtained in DLQI &, PGA. Average remission period after 10th dose was for 30 weeks. Comorbid conditions were not affected by Itolizumab injections.

Conclusion: Itolizumab, a novel anti CD-6, is safe and efficacious in the management of patients with moderate to severe plaque psoriasis with comorbidities.

Disclosure of Interest: None to declare.

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P016

HLA-Cw6, the quintessential psoriasis gene linked to early age of onset, decreased longevity, CV risk and the response to biologic therapy

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Introduction: HLA-Cw6 has been linked to psoriasis (PsO), especially with early age of onset and it is very well documented that PsO has a significant impact on quality of life and is associated with comorbidities like arthritis and cardiovascular disease. Studies suggest that treatment with anti-TNFs could decrease the risk of myocardial infarction (MI).

Objectives: A case-controlled study to test for a significant difference between the risk of suffering cardiovascular events in two groups of patients with severe PsO. Patients who received biologic therapies and patients who did not.

Methods: Cases were extracted from patients' charts at a dermatology clinic (178), controls (440) were obtained from a publicly funded, privacy protected and secure data base.

Results: Early age of onset (before 25 years) was not only linked to HLA-Cw6, but also to a relative risk of suffering a MI of 8.852 ($P<0.05$) (885% increase). Patients with early age of onset had a mean age of death of 59.3 years, which was 11.9 years less than patients whose PsO began after the age of 25 ($P<0.01$). Patients who were Cw6-positive on average died 4.3 years earlier than those Cw6-negative. Cardiovascular disease was the cause of death in 39.2% of patients.
Patients treated with biologic therapy had no increased risk of MI (RR 0.17, $P>0.1$), according to the relative risk calculations of patients on biologic therapy, risk was lowered by 83% (RR 0.176, $P=0.0611$).

Conclusions: HLA-Cw6 is linked to early age of onset of PsO and early age of onset increases the relative risk of MI by 885% in patients with moderate-to-severe PsO. Our data confirms that patients who are HLA-Cw6-positive, on average die 4 years earlier than patients who are Cw6-negative. Early age of onset is associated with 11.9 years of loss of life as compared to other PsO patients and almost 20 years compared to the general population. Our data also confirms observations that biologic therapy does not increase the risk of MI. In fact, biologics significantly decrease the risk of MI (by 83%), and therefore likely has a protective effect against MI and cardiovascular death in moderate-to-severe PsO patients, many who are at risk of MI.

Disclosure of Interest: None to declare.

P017

Prevalence of comorbidities and its relationship to the clinical severity of psoriasis among patients seen in a tertiary hospital

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Background: Psoriasis has been shown to be associated with systemic diseases including hypertension, diabetes, dyslipidemia, obesity, and metabolic syndrome.[1,2]

Objective: To determine the prevalence of comorbidities and its relationship with the clinical severity of psoriasis among patients seen in a tertiary hospital.

Methods: All patients with psoriasis seen from May to July 2013 were included in this study. Patients underwent clinical examination and laboratory examinations including fasting blood sugar and lipid profile. The clinical severity of psoriasis was assessed using the Psoriasis Area and Severity Index (PASI) and percentage of body surface area (BSA) involved. The prevalence of smoking, alcohol consumption, and comorbidities such as elevated blood pressure, diabetes mellitus, dyslipidemia, being overweight, and metabolic syndrome was reported in proportions. The relationship between smoking, alcohol consumption, and comorbidities with psoriasis severity was analyzed using Chi square test and Fisher's exact test.

Results: Among the 72 patients (50% males and 50% females with mean age 45.56 years), 33.33% had hypertension, 22.22% had diabetes mellitus, 72.2% had dyslipidemia, 33.3% were overweight, and 72.2% had metabolic syndrome. Elevated blood pressure ($P=0.0006$), diabetes mellitus ($P=0.0001$), being overweight ($P=0.015$), and metabolic syndrome ($P=0.0001$), were significantly associated with moderate or severe psoriasis.

Conclusions: Psoriasis is significantly associated with comorbidities. Significantly higher proportions of patients with moderate to severe psoriasis are found to be overweight and have elevated blood pressure, diabetes mellitus, and metabolic syndrome.

Disclosure of Interest: None to declare.

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P018

Prevalence of psoriasis and its comorbidities in relatives of psoriatic patients—a cross sectional study from a tertiary center in Northern Greece

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Introduction: Psoriasis is a chronic, inflammatory, multifactorial disease. Genetic predisposition of psoriasis has been indicated by family based studies. Prevalence among first degree relatives varies among different populations worldwide.

Objectives: Aim of this cross–sectional study was to collect data on the prevalence of psoriasis and its comorbidities in first– and second degree relatives of patients with psoriasis from Northern Greece.

Methods: A non–validated questionnaire was handed to 100 patients (57 males and 43 females) who are followed up at the Psoriasis Outpatient Clinic of the 2nd Dermatology Department, Aristotle University School of Medicine in Papageorgiou General Hospital in Thessaloniki, Greece, from May to October 2014. Patients were completing demographic data and answered questions on the medical history of their first– and second degree relatives.

Results: Psoriasis was reported in 14% of first degree patients' relatives, in 15% of second degree patients' relatives and in 9% in both degree relatives. Psoriatic arthritis was reported in 6% of first degree relatives and in 3% of second degree relatives. The most common comorbidities were cardiovascular disease, cancer, dyslipidemia, diabetes mellitus and strokes. Internal malignancies were found in 28% of first degree relatives and in 22% of second degree relatives. Cardiovascular disease was reported in 31% of first degree relatives, in 19% of second degree relatives and in 12% of first and second degree relatives. The less common comorbidities were inflammatory bowel disease and other autoimmune diseases.

Conclusion: As an overall estimate, the most common among the comorbidities in the relatives of psoriatic patients were associated with the risk of metabolic syndrome.

Disclosure of Interest: None to declare.

P019

Psoriasis and comorbidities

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Introduction: In the project were included 42 obese patients with moderate-to-severe chronic plaque psoriasis with systemic treatment. Patients were divided in two groups—exercising with dietary habits change and non-exercising group. During 48 weeks we monitored blood count, biochemical, cytokines; weight loss, BMI, quality of life, PASI. In the control group was included 32 obese exercising persons without psoriasis.

Objectives: The aim was to elicit if the change of dietary habits and lifestyle improves the effect of systemic treatment of psoriasis.

Methods: Patients were treated by systemic treatment. The blood parameters were monitored in weeks 0, 4, 8, 12, 16, 24, 36, 48. The quality of life, PASI and BMI was noticed in week 0 and 48.

Results: We observed significant improvement of average PASI, quality of life, non-significant improvement of BMI in exercising group. In all patients and in the control group was observed similar average weight loss. The level of total cholesterol, HDL and triacylglycerides decrease non-significantly in exercising patients. The sdLDL and LpPLA2 levels were lower during whole 48 weeks in the exercising patients than in the non-exercising. In non-exercising patients the PASI improvement was less significant. We observed decrease of IL-6 level in both groups. The increase of IL-10, TNF-α, adiponectin and leptin levels was noticed in both groups, more in the non-exercising. In control group IL-6 level was lower than in patients. In controls the leptin level was higher than in patients. The TNF-α level in controls was lower than in non-exercising group but comparable with exercising patients.

Conclusion: Marked improvement of PASI, quality of life and also some parameters of metabolic syndrome in exercising patients were observed. The average sdLDL and LpPLA2 levels, risk factors for cardiovascular disease, were lower in exercising patients. We observed increased level of cytokines IL-10 and TNF-α in all patients but more in non-exercising group.

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Disclosure of Interest: None to declare.

P020

Increased risk of herpes zoster among patients with psoriasis: A population-based cohort study in the United Kingdom

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Introduction: Infection is the second leading cause of death among psoriasis patients receiving phototherapy or systemic medications and is an important comorbidity associated with psoriasis. Herpes zoster (HZ) is a common infection, especially among the elderly and those with impaired immunity, and it is associated with potential long-lasting complications and considerable negative impact on quality of life. The risk of HZ among psoriasis patients remains poorly understood.

Objectives: To determine the risk of HZ among patients with versus without psoriasis.

Methods: We conducted a cohort study of patients with ($N=192,986$) and without ($N=893,175$) psoriasis in The Health Improvement Network electronic medical record database in the United Kingdom. Patients receiving phototherapy or systemic therapy were considered to have severe psoriasis ($N=11,918$). The outcome was defined by receipt of a diagnostic code for HZ. We compared rates of HZ between patients with and without psoriasis using multivariable Cox regression.

Results: Among patients <50 years old, the incidence rates of HZ per 1,000 patient years in all patients with psoriasis and those with mild and severe disease versus patients without psoriasis were: 3.1 (95% confidence interval [CI], 3.0–3.3), 3.1 (2.9–3.2), and 4.0 (3.4–4.8) versus 2.6 (2.6–2.7), respectively. Among those ⩾50 years old, the incidence rates were: 8.1 (7.9–8.4), 8.1 (7.8–8.3), and 9.0 (8.0–10.2) versus 6.2 (6.1–6.3). In multivariable analyses adjusting for age, sex, comorbid disease, and systemic corticosteroid use, we found patients with versus without psoriasis to be at increased risk of HZ: hazard ratio 1.28 (95% CI, 1.24–1.32). Risk of HZ was greater among those receiving phototherapy or systemic medications for severe psoriasis: mild, 1.27 (1.24, 1.31); and severe psoriasis 1.41 (1.27–1.56). Vaccination for HZ was reported in only 0.01% of patients with and without psoriasis.

Conclusions: Our results suggest that patients with psoriasis, particularly those receiving treatment for severe disease, are at increased risk of developing herpes zoster.

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P021

Alcohol and psoriasis—the role of signalling neuromediators

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Introduction: Alcohol may worsen psoriasis and increase pruritus. The substance P/neurokinin-1 (NK-1) receptor (R) system may be involved in the control of alcohol intake.

Objectives: To investigate the expression of tachykinins among individuals with psoriasis and correlate the alcohol use with extent of the disease, pruritus and expression of tachykinin markers.

Methods: Fourteen males and fifteen females with moderate to severe psoriasis were recruited. The extent of their disease (PASI), the degree of pruritus (VAS), and their drinking habits using the enquiry Lifetime Drinking History (LDH), were investigated. Phosphatidylethanol (PEth), an alcohol specific biomarker was determined. Biopsies from involved and non-involved skin were analyzed regarding expression of substance P, NKA and the NK-1R, using immunohistochemistry.

Results: Consumption of alcohol as determined by PEth and LDH was found to significantly correlate with the expression of the NK-1R in the apical part of the epidermis in involved and with the NK-1R basal expression in the non-involved skin. There was a reverse correlation between the yearly total units of alcohol ($P = 0.05$), the yearly ($P > 0.01$) and weekly ($P < 0.01$) reported intake of wine and number of NKA positive cells.

Conclusions: The tachykinin system seems to be involved in psoriasis related to the intake of alcohol.

Disclosure of Interest: None to declare.

P022

Cardiovascular disorders in DMARD-naïve patients with active early psoriatic arthritis

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Introduction: Cardiovascular disease (CVD) is the leading cause of death for psoriasis (PsO) and psoriatic arthritis (PsA).

Objective: To evaluate CVD traditional risk factors (TRFs), cardiac and vascular damage in early PsA (EPsA) patients (pts).

Methods: 25 (M/F − 13/12) DMARD-naïve EPsA pts, according to the CASPAR criteria, mean age 36 [27;46] years, PsA duration 5 [3;7] months, PsO duration 36 [12;84] months, DAS 3.9 [3.1;4.7], CRP 15 [9.7;25.1] mg/l were included. CVD TRFs according to ESC (2013), waist circumference (abdominal obesity), body mass index (BMI), ambulatory blood pressure (BP)/24h-ECG monitoring, carotid-intima-media thickness (cIMT) by a high-resolution B-mode ultrasound machine, coronary calcinosis by computer tomography were evaluated. Subclinical atherosclerosis was defined as mean cIMT > 0.9 mm. Me [Q75; Q50], (%), R was calculated. All $P < 0.05$ were considered to indicate statistical significance.

Results: Among early PsA pts, arterial hypertension was identified in 11 (44%) pts, obesity (BMI > 30 kg/m^2) in 7 (28%), abdominal obesity in 14 (56%), smoking in 16 (64%), family history of early CVD in 6 (24%), the increased values of total cholesterol (TC) were found in 14 (56%), low-density lipoproteins (LDL) in 13 (52%), triglycerides in 4 (16%), and the decreased values of high-density lipoproteins (HDL) were found in 4 (16%) pts. CVD TRFs $\geqslant 3$ were observed in 12 (48%) pts. Cardiac arrhythmia (high-degree ventricular extrasystole, runs of supraventricular tachycardia, frequent supraventricular extrasystole) was identified in 12 (48%). Increased cIMT was found in 10 (40%), atherosclerotic plaques—in 8(32%), coronary calcinosis—in 4(16%) pts. Significant positive correlations were found between cIMT and TC ($R = 0.53$), LDL ($R = 0.48$), BP ($R = 0.59$), waist circumference ($R = 0.64$), for all $P \leqslant 0.03$. Significant negative correlations were found between HDL and CRP ($R = -0.52$; $P = 0.03$). 1 woman had history of yearly ischemic brain stroke.

Conclusion: In nearly a half of newly diagnosed PsA pts we found high frequency of CVD TRFs, cardiac and vascular damage which in association with chronic inflammation can accelerate atherosclerosis in pts.

Disclosure of Interest: None to declare.

P023

Itolizumab in management of psoriasis with metabolic syndrome

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Introduction: Itolizumab is a humanized recombinant anti-CD6 monoclonal antibody which exerts an immunomodulatory action on T cells which in turn leads to prolonged control of psoriasis symptoms and lesser incidence of infections. Phase 3 results of Itolizumab showed it to be a promising biologic. Here we present a case where a patient with psoriasis and metabolic syndrome was treated with Itolizumab.

Objectives: To assess the efficacy of Itolizumab in severe psoriasis patient with metabolic syndrome.

Methods: Observational study. Itolizumab was administered as per manufacturer recommendations ie once every fortnight for 3 months followed by once every month for next 3 months. PASI scores were assessed at every infusion visit. Remission period was considered to be duration for which the patients maintained response of PASI 50 after completion of 10 infusions. Adverse events during the treatment period were recorded.

Results: Patient had an initial PASI score of 39.8. PASI scores were 22.2 at completion of 10 infusions. Patient was then administered a maintenance dose of Itolizumab every 3 months. Patient has received 3 maintenance doses till date. Currently the patient's PASI score is 12.2. There was no significant alteration in patient's weight during treatment period.

Conclusion: Patients with psoriasis and metabolic syndrome are difficult to treat. Itolizumab has shown good results in controlling psoriasis in patient with metabolic syndrome once the patient was put on once in 3 months dosage after completion of 10 infusions. These results were achieved without specific diet control measures etc. More studies need to be conducted to study efficacy of Itolizumab in psoriasis and metabolic syndrome.

Disclosure of Interest: None to declare.

P024

Psoriatic arthritis and underlying secondary gout

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Introduction: It is known that there is a correlation between psoriatic arthritis (PsA) and secondary gout. It has been noted to occur in approximately 3 to 4 % of the patients with PsA.[1]

Objective: To demonstrate a higher incidence of different forms of secondary gout in patients with PsA compared to patients with ankylosing spondylitis (AS).

Methods: 92 patients with PsA and a control group of 15 patients with AS were included after signing an informed consent form. The patient history and activity of the disease were verified by validated scores and questionnaires. We used ultrasound (US) scores, biopsy of tophi and polarized light microscopy. We documented 76 (82.6%) patients with PsA and skin lesions and 16 (17.3%) with PsA without skin lesions.

Results: From all 92 patients with PsA 13 showed signs of different forms of secondary gout (14.1%). 5 notified of a typical gouty attack in MTP 1 in the past (according ACR Criteria for Acute Arthritis of Gout from 1977), 6 had ultrasound signs for double contour in the knee joint, 2 had ultrasound tophus-like lesions and hyperechoic spots; 1 had biopsy proved Monosodium urate (MSU) crystals from tophus, 4 had MSU microcrystals in the synovial fluid. 9 of these 13 patients had hyperuricemia. There was only one patient in the control group with signs of secondary gout (6.66%).

Conclusions: In our prospective study we found that PsA was associated with 3 times increased risk of secondary gout compared to the currently available literature data. These results are probably due to the introduction of new methods such as US and biopsy. We considered that the US will be accredited as imaging method for proving the deposition of MSU crystals in the joints and surrounding soft tissues.

Disclosure of Interest: None to declare.

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1. J. F Merola, Sh. Wu, J. Han, H. K Choi, A. A. Qureshi. Psoriasis, psoriatic arthritis and risk of gout in US men and women. *Ann Rheum Dis* (Online First), published on March 20, 2014 as 10.1136.

P025

Psoriatic comorbidities: Patient awareness and provider screening

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Introduction: Numerous bench, clinical and epidemiological studies over the past decade have revealed a host of comorbid diseases associated with psoriasis. Recommendations for screening patients with psoriasis have also been proposed (Lebwohl *et al.*, PUBMED: 24184141). In spite of this, investigation into patient understanding and provider screening of comorbid conditions is lacking.

Objectives: Two objectives were identified:

Analyze awareness of comorbidities among individuals with psoriasis.

Characterize provider screening of comorbidities as reported by patients.

Methods: After three rounds of pre-testing and pilot-testing, an internet link for a survey was emailed to subscribers of the National Psoriasis Foundation's email database. Over three monthly emails, 1,232 of approximately 81,000 in the database reported demographic and comorbid information, including awareness of seven comorbidities, type of provider seen and frequency of provider screening by comorbid condition.

Results: Awareness of a higher risk of painful and swollen joints and mood disorders were the only comorbid conditions among seven in which greater than 50% of respondents were aware. With the exception of painful and swollen joints, ''Never'' was the most common frequency of screening for mood disorders, high blood pressure, diabetes and nail and genital involvement. Among patients with self-reported diabetes, hypertension, obesity and smoking, the most common frequency of screening was ''Never.'' Screening of comorbid conditions varied by provider subtype with rheumatologists screening to the greatest extent and physician assistants and nurse practitioners screening the least.

Conclusions: Despite an established body of evidence supporting numerous comorbidities in psoriasis, patient awareness of comorbid conditions remains low. While screening for comorbid conditions was elevated among rheumatologist and dermatologists in academic practice, screening for comorbidities across all provider types was lacking. Screening for hypertension, diabetes, obesity and smoking was low even among respondents with the comorbidity.

Disclosure of Interest: None to declare.

CURRENT AND NEW THERAPEUTIC MODALITIES

P026

Efficacy and safety of Indigo naturalis extract in oil ointment in treating Psoriasis Vulgaris: A randomized, double-blind, four-arm comparative trial

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Background: Indigo naturalis is effective in improving psoriatic symptoms and the refined formulation in oil, Lindioil, is as effective as the crude form.[1] The active ingredient, indirubin, plays a major role in treating psoriasis; however, the most effective and safest dosage of indirubin is unknown.

Objective: To determine the effective and safe dosage of indirubin in the Lindioil ointment for treating psoriasis among four dosages.

Methods: One hundred subjects with chronic plaque psoriasis were enrolled and randomized into four different indirubin dosage groups: 200, 100, 50, or 10 μg/g. Ointment was applied topically to psoriatic lesions twice a day for 8 weeks and followed up for another 12 weeks. The efficacy was evaluated using Psoriasis Area and Severity Index (PASI), Body Surface Area (BSA) involvement and Physician's Global Assessment (PGA).

Results: One-hundred subjects were randomized into 25 subjects per group, 91 subjects completed the 8-week treatment and 76 subjects completed the 12-week follow-up. The reduction percentage for PASI scores across the four groups from baseline to week 8 was 69.2%, 63.1%, 50.2%, and 53.9%, respectively ($P=0.0595$). The percentage of subjects whose PASI scores achieved improvement >90% within the four groups were 30.4%, 8.0%, 4.0% and 4.0%, respectively ($P=0.0098$). The reduction percentage for BSA within the four groups was 64.7%, 44.5%, 41.0% and 39.4%, respectively ($P=0.0322$). The percentage of subjects whose PGA achieved ''almost clear and no sign of psoriasis'' within the four groups at week 8 were 52.2%, 48.0%, 24.0% and 20.0%, respectively ($P=0.098$). No severe adverse events related to the treatment were reported within the 20-week trial.

Conclusions: Lindioil ointment is a safe and effective topical medication in treating patients with skin psoriasis and the 200 μg/g of indirubin in the Lindioil ointment is the most effective dosage.

Disclosure of Interest: None to declare.

References:

1. Lin YK, *et al.* Comparison of refined and crude indigo naturalis ointment in treating psoriasis: randomized, observer-blind, controlled, intrapatient trial. *Arch Dermatol.* 2012;148(3):397–400.

P027

Association of touch avoidance with disease severity and quality of life in psoriasis patients

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Introduction and Objectives: A cross-sectional survey was conducted among patients with psoriasis (Ps) and included questions to assess the avoidance of interpersonal touch and its association with disease severity and quality of life.

Methods: An online survey consisting of various patient-reported outcome instruments, including the DLQI and the QIDS, was conducted during October and November 2013. Participants ($n=1109$) were asked to rate over the past two weeks whether they had avoided touching others or others touching them (eg shaking hands or hugging) because of the way their skin looks or feels (0 [not at all] to 10 [very much]). Participants were divided into two groups: ''no touch avoidance'' (0) or ''touch avoidance'' (>0). Disease severity was assessed according to participants' estimated body surface area (BSA) affected by Ps and a patient-rated global assessment of disease severity that ranged from 0 (clear) to 5 (severe). Associations between touch avoidance and other outcome measures were tested using unadjusted CMH chi-square tests and logistic model after adjusting for age, gender, presence of psoriatic arthritis, duration of disease, and BSA, if applicable.

Results: Approximately half (48.2%) of participants reported touch avoidance. Gender and marital status had no significant impact on touch avoidance. Younger participants had significantly more touch avoidance compared to older participants ($P<0.05$). Those reporting itch avoided touch more than those without itching ($P<0.05$). Touch avoidance was significantly associated with disease severity, using both the BSA and 0–5 disease severity scales ($P<0.05$). Participants with Ps on hands, neck, feet, or nails were more likely to avoid touch than those without Ps in those locations. Participants reporting touch avoidance were significantly more likely to have worse quality of life (as measured by DLQI, $P<0.05$), and more likely to have depression, compared to those with no touch avoidance ($P<0.05$).

Conclusions: These data indicate that for patients with Ps, touch avoidance is associated with disease severity, location of psoriasis on the body, and worsened quality of life, including depression.

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P028

Efficacy of ixekizumab in patients with and without previous experience with biologic therapies compared to etanercept and placebo: results from UNCOVER-2, a phase 3 trial in patients with plaque psoriasis

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Introduction and objectives: Ixekizumab is an anti-IL-17A monoclonal antibody. This subgroup analysis evaluated the efficacy of ixekizumab compared with placebo and etanercept in patients (pts) with moderate to severe plaque psoriasis with or without previous experience with biologic therapy.

Methods: 1,224 pts were randomized to receive either placebo ($N=168$), or etanercept 50 mg bi-weekly ($N=358$), or ixekizumab 80 mg subcutaneously once every 2 weeks (IXE Q2W, $N=351$) or 4 weeks (IXE Q4W, $N=347$) after an initial dose of 160 mg at Week 0. At Week 12, the proportions of pts with at least ⩾75% improvement in Psoriasis Area and Severity Index (PASI 75); a static physician global assessment of 0 or 1 (sPGA 0,1); and a 100% improvement in PASI (PASI 100) were evaluated in subgroups of pts with previous exposure to biologics and pts naïve to biologic therapy. Treatment groups were compared using Fisher's exact test within each subgroup and missing values were imputed as non-response.

Results: Overall, 288 pts had received prior biologic treatment and 936 were biologic-naïve. In both subgroups, respective PASI 75 response rates with IXE Q2W (92.9% and 88.8%) and IXE Q4W (74.1% and 78.6%) were significantly greater than those with placebo (0% and 3.2%, $P<0.05$) and etanercept (30.3% and 44.3%, $P<0.05$). Similarly, sPGA 0,1 response rates with IXE Q2W (84.5% and 82.8%) and IXE Q4W (67.1% and 74.8%) were significantly greater than those with placebo (0% and 3.2%) and etanercept (30.3% and 37.6%). The respective proportions of pts with PASI 100 in the biologic-experienced and biologic-naïve subgroups were also significantly higher with IXE Q2W (48.8% and 37.8%) and IXE Q4W (22.4% and 33.6%) compared with placebo (0% and 0.8%, $P<0.05$) and etanercept (5.3% and 5.3%, $P<0.05$).

Conclusions: In this subgroup analysis, both ixekizumab dose regimens (IXE Q2W and IXE Q4W) were significantly more effective in the treatment of psoriasis than either placebo or etanercept in pts who had prior exposure to biologic therapy or who were biologic-naïve.

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P029

Ixekizumab for treatment of moderate-to-severe plaque psoriasis: 12-week results from a phase 3 study (UNCOVER-1)

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Introduction: IL-17A plays a major role in the pathogenesis of psoriasis.

Objective: The objective of this study was to evaluate efficacy and safety of ixekizumab, an anti-IL-17A monoclonal antibody, in the treatment of psoriasis compared to placebo over 12 weeks.

Methods: In this multicenter, double-blind trial, 1,296 patients were randomized to receive subcutaneous placebo ($N=431$), or 80 mg IXE as one subcutaneous injection every 2 (IXE Q2W, $N=433$) or 4 weeks (IXE Q4W, $N=432$) following a 160 mg initial dose at Week 0. The co-primary efficacy endpoints were the proportion of patients who achieve 1) an sPGA 0/1, and 2) PASI 75 by Week 12. Comparisons were done using logistic regression analysis, or Fisher's exact test. For response analyses, missing data was imputed using non-responder imputation.

Results: At Week 12, PASI 75 was achieved by 89.1% and 82.6% of patients receiving IXE Q2W and IXE Q4W, respectively, compared to 3.9% in patients receiving placebo ($P<0.001$). sPGA 0/1 was achieved by 81.8% and 76.4% of patients receiving IXE Q2W and IXE Q4W, respectively, compared to 3.2% patients in patients receiving placebo ($P<0.001$). Statistically significant differences were observed as early as Week 1 for both ixekizumab groups compared to the placebo group ($P<0.001$). Complete resolution of psoriasis (PASI 100) was achieved by 35.3% and 33.6% of patients receiving IXE Q2W and IXE Q4W, respectively, compared to 0 patients receiving placebo ($P<0.001$). Treatment-emergent adverse events reported in ⩾5% of all ixekizumab-treated patients and at higher percentages than in placebo-treated patients included nasopharyngitis, upper respiratory tract infection, and injection-site reaction and erythema. Most of these events were mild to moderate in severity. Serious adverse events were seen in 1.4%, 2.8%, and 1.2% of patients in the IXE Q2W, IXE Q4W and placebo groups, respectively; no deaths were reported.

Conclusions: Both ixekizumab dosing regimens resulted in rapid and significant improvements in psoriasis, and safety results in this study were comparable to those in other Phase 3 studies with ixekizumab.

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P030

Canadian Humira post-marketing observational epidemiological study assessing effectiveness in psoriasis (COMPLETE-PS): Preliminary analysis

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Introduction: COMPLETE-PS is an ongoing observational study planned to enroll 660 psoriasis (PS) patients (pts) from ~40 sites across Canada. Main objectives are to compare the real-life effectiveness of adalimumab (ADA) to topical and traditional systemic (TTS) agents and to describe the PS burden of illness.

Objectives: To describe the demographics and baseline disease parameters of the cohort; to report preliminary data on the real-life effectiveness of ADA in PS.

Methods: Pre-specified interim analysis in 306 pts (ADA, $n=153$; TTS, $n=153$) enrolled 8/2011 – 5/2014. Eligible pts must be adults; have active moderate-to-severe plaque PS; and require change in current PS treatment. Pts are followed for ⩽2 years per routine clinical care. Parameters captured include disease activity (physician [PGA] and patient [PtGA] global assessment, PS BSA, PASQ, and DLQI), quality of life (SF-36, BDI-II), and work limitations (WLQ).

Results: At baseline, mean (SD) age was 49.7 (14.3) years; the majority were male (62.7%) without significant differences between groups. Mean (SD) years from diagnosis (17.7 [14.1]) and family history of PS (55.6%) were also comparable.

ADA pts had more flare-ups 12 months prior to enrollment (5.5 versus 2.9; $P=0.010$) and more commonly had concomitant psoriatic arthritis (41.3% versus 15.5%; $P<0.001$) compared with TTS pts. Furthermore, ADA pts had significantly higher BSA (21.0% versus 17.8%; $P=0.012$), PASQ (7.4 versus 5.8; $P=0.003$), and DLQI (13.2 versus 9.8; $P<0.001$) scores, and PtGA (58.7 versus 50.0 mm; $P=0.014$), but comparable PGA, BDI-II, SF-36, and WLQ scores.

Over 6 months, significant improvements were observed in almost all parameters, which were sustained or enhanced over time. Upon adjusting for baseline values, ADA pts had significantly lower PGA (1.2 versus 2.1; $P<0.001$), PtGA (26.3 versus 38.5 mm; $P<0.001$), BSA (3.7% versus 7.5%; $P=0.002$), PASQ (5.8 versus 6.5; $P=0.016$), and DLQI (3.0 versus 6.7; $P<0.001$) at 6 months compared with TTS pts.

Conclusions: PS pts initiating ADA in Canadian routine clinical care have more severe disease compared with those initiating TTS agents. However, ADA treatment was more effective in reducing symptom severity and improving outcomes over time.

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P031

Direct access transient elastography for methotrexate-induced liver fibrosis

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Introduction: Usage of methotrexate in psoriasis is limited by liver toxicity. Liver biopsy remains the gold standard for diagnosing methotrexate-induced liver fibrosis but is associated with patient discomfort and morbidity. Transient elastography (TE) is an alternative, rapid, non-invasive method. Scheduling of TE poses a significant barrier. Patients at a tertiary dermatology referral centre required a total of three visits for TE to be actualised; consult with gastroenterologist, TE scan on a separate date and another appointment to review results with the gastroenterologist.

Objectives: We present a review of TE for psoriasis patients on methotrexate and describe a direct access scheme.

Methods: Review of the literature for evidence for cutoff values of TE results, comparison of guidelines (British, Dutch, EU, German and American) for evaluation and monitoring of hepatotoxicity in psoriasis patients receiving methotrexate. We describe the new workflow for obtaining TE for psoriasis patients which allows the patient to have TE (FibroScan) performed directly at a neighbouring hospital and the results to be uploaded to the patient's electronic medical records for review by the dermatologist.

Results: From the inception of the direct access programme on 1 Sep 2014 to 1 Mar 2015, 4 patients under one of the authors (HHO) have undergone direct access TE with an average waiting time of 9.75 days from appointment booking to the test date. This is a significant reduction from the mean waiting time of 69.33 days.

Conclusion: Direct access to TE for psoriasis patients reduces waiting time for testing and unnecessary gastroenterology appointments. Such joint collaborative efforts are important in providing seamless quality care for psoriasis patients.

Disclosure of Interest: None to declare.

P032

A Phase 2b dose-ranging trial of baricitinib, an oral JAK 1/JAK 2 inhibitor, in patients with moderate-to-severe psoriasis: Results from the randomized withdrawal and re-treatment periods

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Introduction: Baricitinib (BARI) was evaluated in a 4-part study. Parts A and B have been reported.[1] 271 patients (pts) were randomized 1:1:2:2:2 to placebo (PBO) or BARI 2 or 4 mg (low dose [L]) or 8 or 10 mg (high dose [H]) for 12 weeks (Part A). Dose adjustments for an additional 12 weeks of treatment were based on % improvement in Psoriasis Area and Severity Index (PASI) (Part B). Parts C and D are reported.

Objectives: To determine, in patients who achieved a PASI 75 response at the end of Part B (responders), time to relapse (TTR, ⩾50% baseline disease severity) following treatment with ½ dose BARI or placebo (Part C). Re-treatment efficacy was assessed in pts with relapse (Part D).

Methods: Part B responders were randomized 1:1 to ½ dose BARI (10 mg received 4 mg; L→½L $n=16$; H→L $n=55$) or PBO (L→PBO $n=15$; H→PBO $n=55$). TTR was assessed over 4 months. Pts with relapse were re-treated at the Part B effective dose (2 mg $n=3$; 4 mg $n=13$; 8 mg $n=19$; 10 mg $n=37$) for another 52 weeks. Treatment comparisons used Fisher's exact/log-rank tests; estimates were from Kaplan-Meier curves.

Results: In Part C, 60% of L→PBO and 37.5% of L→½L relapsed ($P=0.289$) while 65.5% of H→PBO and 30.9% of H→L relapsed ($P<0.001$). Median TTR was 61–70 days on PBO versus ⩾112–117 days on ½ dose. Two H→PBO and 2 H→L patients discontinued due to adverse events (DCAE). One H→PBO and 1 H→L pt had a serious AE (SAE). In Part D, PASI 75 was achieved by 100%, 69.2%, 52.6%, 81.1% of 2, 4, 8, 10 mg pts. Median time to re-treatment response was 85–87 days for all treatments except 8 mg (166 days). Re-treatment response (non-responder imputation) was 67%, 46%, 37%, 49% (week 12) and 0%, 15%, 32%, 54% (week 52) for 2, 4, 8, 10 mg pts. DCAEs were 0/3, 1/13, 1/19, and 3/37 for 2, 4, 8, 10 mg pts. One 8 mg pt had an SAE.

Conclusions: Responders given a step-down dose during Part C had lower relapse rates and longer TTR versus PBO. After 12 weeks of re-treatment during Part D, 37–67% of pts achieved a PASI 75 response. There were no new safety findings.

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P033

Real-world validation of the minimal disease activity index in psoriatic arthritis: An analysis from a prospective, observational registry

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Introduction: The definition of minimal disease activity (MDA) in PsA includes fulfillment of ⩾5 of the 7 following criteria: tender joint count (TJC) ⩽ 1, swollen joint count (SJC) ⩽ 1, PASI ⩽ 1 or body surface area ⩽ 3%, pain (VAS) ⩽ 15, patient global disease activity (PtGA) (VAS) ⩽ 20, HAQ ⩽ 0.5, and tender entheseal points ⩽1 (1).

Objectives: To describe the rate of MDA achievement over time and to assess the association between MDA and DAS28 remission in PsA patients treated with Infliximab (IFX) or golimumab (GLM) in a routine clinical practice setting.

Methods: BioTRAC is an ongoing, prospective registry of patients initiating treatment for RA, AS or PsA with IFX or GLM as first biologics. Data from PsA patients who had available MDA information at baseline, 6 months, and/or 12 months were included. Improvement in patient parameters over time was assessed for statistical significance with the paired-samples *t*-test. Agreement between MDA and DAS28 remission <2.6 was assessed.

Results: 123 PsA patients with mean (SD) age of 50.5 (10.5) yrs and mean (SD) dis duration of 6.1 (7.3) yrs were included. At baseline, mean (SD) patient parameters were: DAS28 = 4.2 (1.5), PASI = 2.7 (4.8), SJC28 = 4.1 (3.5), TJC28 = 6.1 (5.6), morning stiffness = 45.4 (43.0) min, HAQ-DI = 1.09 (0.65), MDGA = 5.3 (2.1), PtGA = 49.3 (27.3) mm, and pain = 46.5 (25.2) mm. By 6 mos of treatment, statistically significant ($P<0.05$) improvements were observed in all clinical and patient outcome parameters studied, which were sustained or further enhanced over 12 months of treatment. The proportion of patients with MDA significantly increased from 12.3% at baseline to 45.0% after 6 mos of treatment ($P<0.001$), and 41.9% at 12 mos ($P=0.021$). Similarly, DAS28 remission was observed in 15.9%, 47.8% and 45.1% of patients at baseline, 6 mos, and 12 mos, respectively. Using DAS28 as reference standard, sensitivity was 69.8%, specificity 93.0%, NPV 88.2%, and PPV 80.4%.

Conclusions: MDA has high discriminatory power for remission while being more rigorous than DAS28. Furthermore, treatment with anti-TNF is effective in inducing MDA in 45% of patients as early as 6 mos from treatment initiation.

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P034

Tofacitinib exposure-response characteristics in patients with moderate to severe chronic plaque psoriasis

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Introduction: Tofacitinib is an oral Janus kinase inhibitor that is being investigated for psoriasis.

Objectives: To evaluate the longitudinal relationship between tofacitinib exposure and clinical response.

Methods: Data for this analysis were pooled from a Phase 2b (NCT00678210) and four Phase 3 studies (NCT01276639, NCT01309737, NCT01241591, NCT01186744). A non-linear, longitudinal exposure-response model for Psoriasis Area and Severity Index (PASI) improvement was used to describe dose- and time-dependent changes. Selected patient (pt) characteristics were evaluated as predictors of response.

Results: The analysis included 3,431 pts with 17221 observations. Average systemic blood levels (Cavg) did not improve predictions relative to dose. For a typical pt (male; body weight, 86 kg; baseline PASI, 20; biologic agent-naïve), 49% and 61% of pts receiving tofacitinib 5 and 10 mg BID, respectively, were predicted to achieve ⩾75% improvement from baseline in PASI score at Week 16; this corresponded to ~65% and 81% of the maximum effect (Emax) on the dose-response curve. Covariate evaluation suggested that heavier pts required a higher dose to achieve a similar response to lighter pts; a doubling of body weight (eg from 60 to 120 kg) increased the dose needed to achieve 50% of Emax (ED50) 1.8-fold (90% CI 1.45, 2.20). This relationship could not be attributed to differences in pharmacokinetics (Cavg) with weight. ED50 was also lower for pts who were female, biologic agent-naïve or had higher baseline PASI; higher baseline PASI also resulted in slower onset of effect. Higher body weight and prior biologic use substantially reduced absolute clinical response. Dose response was evident in the above subpopulations; 10 mg BID consistently provided clinically meaningful higher response versus 5 mg BID.

Conclusions: Although significant improvements were observed with both tofacitinib doses, dose-response characterisation in pts with psoriasis showed that tofacitinib response was reduced with higher body weight and prior biologic experience, as seen with other psoriasis therapies. Tofacitinib 10 mg BID provided clinically meaningful benefit over 5 mg BID in these subpopulations.

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P035

Efficacy and safety of brodalumab in patients with moderate to severe plaque psoriasis: Results of AMAGINE-1, a phase 3, randomized, double-Blind, placebo-controlled study

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Introduction: AMAGINE-1 evaluated the efficacy and safety of brodalumab, a human anti-IL-17 receptor A monoclonal antibody, for moderate to severe psoriasis.

Objectives: Report week 12 (induction phase) results for: PASI75 and sPGA 0/1 (static physician global assessment, 6 Point scale) [co-primary endpoints]; Psoriasis Symptom Inventory (PSI) response (total score ⩽8, no item score >1) [key secondary]; Dermatology Life Quality Index (DLQI) 0/1; improvement in Hospital Anxiety and Depression Scale (HADS).

Methods: Subjects were randomized (1:1:1) to brodalumab 210 or 140 mg Q2W or placebo [PBO]. Data were analyzed with a Cochran-Mantel-Haenszel test (PASI, sPGA, PSI, DLQI; non-responder imputation) or ANCOVA model (HADS; multiple imputation), adjusted for baseline weight, prior biologic use, geographic region, and endpoint baseline value.

Results: Of 661 subjects randomized, 633 completed week 12. Mean (SD) baseline scores were: PASI, 19.7 (7.3); PSI, 19.2 (6.9); DLQI, 14.1 (7.2); HADS anxiety and depression, 6.6 (4.1) and 5.3 (4.1). Week 12 results are shown below. The estimated difference (95% CI) between the 210 mg group and PBO for improvement in HADS anxiety and depression scores was 2.1 (1.5, 2.7) and 1.5 (0.9, 2.1) [unadjusted $P<0.001$; similar estimated difference for the 140 mg group]. AE and SAE rates were 59%, 58%, and 51% and 1.8%, 2.7%, and 1.4% in the 210 mg, 140 mg, and PBO groups, with 1 AE each of neutropenia (140 mg) and decreased absolute neutrophil count (210 mg). Potential candida infections were reported by 2.3%, 0.5% and 1.4% of patients in the 210 mg, 140 mg and PBO groups.

Conclusion: Brodalumab treatment resulted in significant improvement in clinical and patient reported outcomes, with no negative impact on patient-reported anxiety and depression. AEs were consistent with prior reports.

Disclosure of Interest: K. Papp Grant/Research support from: AbbVie, Amgen Inc., Astellas Pharma, Bayer AG, Boehringer Ingelheim, Celgene, Forward Pharma, Galderma, Janssen Biotech Inc., Eli Lilly and Company, LEO Pharma, Merck, Novartis, Pfizer, Roche, and UCB Pharma, Consultant of: AbbVie, Amgen Inc., Astellas Pharma, Bayer AG, Boehringer Ingelheim, Celgene, Forward Pharma, Galderma, Janssen Biotech Inc., Eli Lilly and Company, LEO Pharma, Merck, Novartis, Pfizer, Roche, and UCB Pharma, Speakers bureau of: AbbVie, Amgen Inc., Astellas Pharma, Bayer AG, Boehringer Ingelheim, Celgene, Forward Pharma, Galderma, Janssen Biotech Inc., Eli Lilly and Company, LEO Pharma, Merck, Novartis, Pfizer, Roche, and UCB Pharma; K. Reich Consultant of: AbbVie, Amgen, Biogen-Idec, Celgene, Centocor, Covagen, Forward Pharma, GlaxoSmithKline, Janssen-Cilag, LEO Pharma, Lilly, Medac, MSD, Novartis, Ocean Pharma, Pfizer, Regeneron, Takeda, Vertex, Speakers bureau of: AbbVie, Amgen, Biogen-Idec, Celgene, Centocor, Covagen, Forward Pharma, GlaxoSmithKline, Janssen-Cilag, LEO Pharma, Lilly, Medac, MSD, Novartis, Ocean Pharma, Pfizer, Regeneron, Takeda, Vertex; C. Leonardi Grant/Research support from: Abbott, Amgen, Celgene, Centocor, Eli Lilly Galderma, Genentech, Genzyme, GlaxoSmithKline, Incyte, Janssen, Maruho, Novartis, Novo Nordisk, Pfizer, Schering Plough, Sirtris, Stiefel, Vascular Biogenics and/or Wyeth, Consultant of: Abbott, Amgen, Celgene, Centocor, Eli Lilly Galderma, Genentech, Genzyme, GlaxoSmithKline, Incyte, Janssen, Maruho, Novartis, Novo Nordisk, Pfizer, Schering Plough, Sirtris, Stiefel, Vascular Biogenics and/or Wyeth, Speakers bureau of: Abbott, Amgen, Celgene, Centocor, Eli Lilly Galderma, Genentech, Genzyme, GlaxoSmithKline, Incyte, Janssen, Maruho, Novartis, Novo Nordisk, Pfizer, Schering Plough, Sirtris, Stiefel, Vascular Biogenics and/or Wyeth; C. Paul Grant/Research support from: Amgen Inc, A. Blauvelt Grant/Research support from: AbbVie, Amgen, Anacor, Boehringer Ingelheim, Celgene, Genentech, Janssen, Lilly, Merck, Novartis, Pfizer, Regeneron, Sandoz; W. Baran Consultant of: Amgen; C. Bolduc Grant/Research support from: Abbott, Amgen, Pfizer, Celgene, Leo Pharma, Eli Lilly; D. Toth: None to declare; R. G. Langley Grant/Research support from: AbbVie, Amgen, Celgene, Leo, Lily, Merck, Novartis, Pfizer, Speakers bureau of: AbbVie, Amgen, Celgene, Leo, Merck, Novartis, Pfizer; J. Cather: None to declare; A. Gottlieb Grant/Research support from: Centocor (Janssen), Amgen, Abbott (Abbvie), Novartis, Celgene, Pfizer, Lilly, Coronado, Levia, Merck, Xenoport, Consultant of: Amgen Inc.; Astellas, Akros, Centocor (Janssen), Inc.; Celgene Corp., Bristol Myers Squibb Co., Beiersdorf, Inc., Abbott Labs. (Abbvie), TEVA, Actelion, UCB, Novo Nordisk, Novartis, Dermipsor Ltd., Incyte, Pfizer, Canfite, Lilly, Coronado, Vertex, Karyopharm, CSL Behring Biotherapies for Life, Glaxo Smith Kline, Xenoport, Catabasis, Sanofi Aventis, DUSA; D. Thaci Speakers bureau of: Amgen, AbbVie, MSD, Janssen-Cilag, Pfizer, Novartis, biogen-idec, Celgene, Leo; C. E. Milmont Shareholder of: Amgen, Employee of: Amgen; J. Li Shareholder of: Amgen, Employee of: Amgen; P. Klekotka Shareholder of: Amgen, Employee of: Amgen; G. Kricorian Shareholder of: Amgen, Employee of: Amgen; A. Nirula Shareholder of: Amgen, Employee of: Amgen.

[P035] Table 1. Week 12 Response Rates (95% CI)

	Brodalumab		Placebo ($N=220$)
	210 mg Q2W ($N=222$)	140 mg Q2W ($N=219$)	
PASI75*	83 (78, 88)	60 (54, 67)	3 (1, 6)
sPGA 0/1*	76 (70, 81)	54 (47, 61)	1 (0, 4)
PASI100*	42 (35, 49)	23 (18, 30)	1 (0, 3)
PSI response*	61 (54, 67)	53 (46, 60)	4 (2, 8)
PASI90†	70 (64, 76)	43 (36, 49)	1 (0, 3)
DLQI 0/1†	56 (49, 63)	43 (36, 50)	5 (3, 9)

*Adjusted $p<0.001$; †Unadjusted $p<0.001$.

P036

Pregnancy outcomes in the tofacitinib psoriasis safety database up to April 2014

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Introduction: Tofacitinib is an oral Janus kinase inhibitor that is being investigated for psoriasis. No adverse foetal effects were observed in preclinical studies with exposures corresponding to the human dose tofacitinib 10 mg BID; at approximately >10 and 100-fold this exposure, tofacitinib was teratogenic (visceral and skeletal abnormalities) in rabbits and rats, and decreased the number of viable pups in rats. There are no well-controlled tofacitinib studies in pregnant women; the psoriasis clinical development programme excluded pregnant patients (pts) and required contraception use. If a patient became pregnant, treatment discontinuation was mandatory. Pregnancies were followed up to investigate occurrence of any adverse outcomes.

Objectives: To understand potential effects of tofacitinib on pregnancy outcomes in pts with psoriasis.

Methods: Cases were identified from Pfizer's internal safety database, including all tofacitinib exposure in clinical studies through April 2014. Cases included females administered study medication at time of conception and/or foetuses exposed to study medication through maternal or paternal exposure. Pregnancy outcomes were categorised as healthy newborns, spontaneous abortion, medical termination, pending, or lost to follow-up.

Results: In total 16 female pts, aged 19–40 years, became pregnant while on study drug over the course of 5203.6 patient-years of tofacitinib exposure. Most pts were treated with tofacitinib at the time of conception and early gestation. There were no cases of foetal demise or birth defects reported among these 16 pts; 4 abortions (1 spontaneous, 3 elective) were reported. All other pts had healthy newborns (6), had not yet reported pregnancy outcome (5), or were lost to follow-up (1). There were 42 cases of paternal exposure to tofacitinib: 13 healthy newborns, 5 spontaneous abortions, 19 pending outcome, and 5 lost to follow-up.

Conclusions: No pregnancies resulting in birth defects or foetal demise were reported among cases of maternal tofacitinib exposure. Pregnancy outcomes reported here were generally similar to those reported with biologic psoriasis therapies, and in tofacitinib-treated RA pts.

Disclosure of Interest: S. Feldman Consultant of: AbbVie, Amgen, Celgene, Galderma, Merck, Novartis, Pfizer Inc, Speakers bureau of: Celgene, Galderma, Janssen; A. B. Kimball Consultant of: AbbVie, Amgen, Eli Lilly, Novartis, Pfizer Inc; R. B. Warren Grant/Research support from: AbbVie, Novartis, Pfizer Inc, Consultant of: AbbVie, Amgen, Celgene, Eli Lilly, Janssen, Novartis, Pfizer Inc, Speakers bureau of: AbbVie, Amgen, Celgene, Eli Lilly, Janssen, Novartis, Pfizer Inc; D. Frazier Shareholder of: Pfizer Inc, Employee of: Pfizer Inc; J. Proulx Shareholder of: Pfizer Inc, Employee of: Pfizer Inc; A. Marren Shareholder of: Pfizer Inc, Employee of: Pfizer Inc.

P037

Efficacy of tofacitinib for the treatment of nail psoriasis: two 52-week phase 3 studies in patients with moderate to severe plaque psoriasis

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Introduction: Tofacitinib is an oral JAK inhibitor that is being investigated for psoriasis; Phase 3 studies have shown efficacy and safety of tofacitinib in patients (pts) with psoriasis.

Objectives: This is a post-hoc analysis of Nail Psoriasis Severity Index (NAPSI) in pts with existing nail psoriasis from two 52-week Phase 3 pivotal studies in moderate to severe plaque psoriasis (OPT Pivotal 1, NCT01276639; OPT Pivotal 2, NCT01309737).

Methods: Adult pts were randomised 2:2:1 to receive tofacitinib 5, 10 mg, or placebo, BID. At Week 16, placebo pts were re-randomised to tofacitinib 5 or 10 mg BID. Change in NAPSI score and proportions achieving ⩾75% reduction in NAPSI (NAPSI75) or NAPSI100 at Weeks 16 and 52 were assessed; for NAPSI75 and NAPSI100 non-responder imputation was applied. Data were pooled from the studies; nominal *P* values for treatment comparisons presented for Week 16.

Results: 1,196 (64%) pts had nail psoriasis: 487 (5 mg BID), 476 (10 mg BID) and 233 (placebo). These pts were aged 46.0 years (median), 77% were male, 80% were white, 24% also had psoriatic arthritis, median PASI score was 20. Mean [standard error; SE] number of nails affected at baseline were 7.3 [0.1] (5 mg BID), 7.3 [0.1] (10 mg BID), 7.4 [0.3] (placebo to 5 mg BID) and 7.3 [0.3] (placebo to 10 mg BID). Baseline mean [SE] NAPSI scores were 27.0 [0.9] (5 mg BID), 27.3 [1.0] (10 mg BID), 26.0 [2.0] (placebo to 5 mg BID) and 25.5 [1.8] (placebo to 10 mg BID).

Conclusions: Tofacitinib led to significant improvements in NAPSI at 16 weeks which were maintained for 52 weeks in pts with moderate to severe plaque psoriasis with nail psoriasis.

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[P037] Table 1. Results at Weeks 16 and 52

Week 16	5 mg BID	10 mg BID	Placebo
Least squares mean % change from baseline NAPSI score, mean [SE]	-17.4 [6.1]*	-34.2 [6.1]*	35.0 [9.3]
NAPSI75, % [SE]	16.9 [1.7]*	28.1 [2.1]*†	6.8 [1.7]
NAPSI100, % [SE]	10.3 [1.4]*	18.2 [1.8]*†	5.1 [1.4]

*$P<0.01$ versus placebo; †$P<0.01$ versus 5 mg BID.

[P037] Table 2

Week 52	5 mg BID	10 mg BID	Placebo to 5 mg BID	Placebo to 10 mg BID
Mean % change from baseline NAPSI score [SE]	-65.6 [3.7]	-75.5 [2.5]	-51.8 [26.5]	-72.7 [4.9]
NAPSI75, % [SE]	24.6 [2.0]	41.0 [2.3]	37.7 [5.5]	35.6 [4.8]
NAPSI100, % [SE]	16.4 [1.7]	29.2 [2.1]	24.7 [4.9]	23.8 [4.2]

P038

Safety of tofacitinib, an oral Janus kinase inhibitor, for the treatment of chronic plaque psoriasis: integrated data analysis from the global clinical trials

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Introduction: Tofacitinib is an oral Janus kinase inhibitor being investigated for psoriasis.

Objectives: We report pooled trial safety data.

Methods: Patients received tofacitinib 5 or 10 mg BID in one Phase 2 (P2) and three 1-year Phase 3 (P3) randomised controlled trials (1Y-RCTs). In a long-term extension (LTE) study, patients received 10 mg BID (3 months), then 5 or 10 mg BID (ongoing, database not locked, data cut-off April 4, 2014). Incidence rates (IR; patients with events/100 patient-years) were calculated for 1Y-RCTs and overall exposure (P2 + P3 + LTE). P2 + P3 + LTE doses were pooled.

Results: 3,623 patients received tofacitinib (median days of tofacitinib exposure: 527, range: 1–1344, quartiles 1 and 3: 261, 766). Serious infection IRs were 1.37 and 2.42 with 5 and 10 mg BID (1Y-RCTs), and 1.68 (P2 + P3 + LTE). Herpes zoster IRs were 1.00 and 2.32 with 5 and 10 mg BID (1Y-RCTs), and 2.55 (P2 + P3 + LTE). Malignancy (excluding non-melanoma skin cancer [NMSC]) IRs were 1.12 and 0.81 with 5 and 10 mg BID (1Y-RCTs), and 1.00 (P2 + P3 + LTE). NMSC IRs were 0.63 and 1.27 with 5 and 10 mg BID (1Y-RCTs), and 0.74 (P2 + P3 + LTE). Major adverse cardiovascular event IRs were 0.50 and 0.23 with 5 and 10 mg BID (1Y-RCTs), and 0.37 (P2 + P3 + LTE). In 1Y-RCTs, 95% CIs for 10 versus 5 mg BID hazard ratios included 1 for each of these events.

Conclusions: Serious infection, herpes zoster, NMSC IRs were numerically, but not statistically, higher with 10 versus 5 mg BID. IRs were stable over time in P2 + P3 + LTE.

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P039

Efficacy, safety and patient-reported outcomes up to 52 weeks with tofacitinib, an oral Janus kinase inhibitor, for the treatment of chronic plaque psoriasis: results from two randomised, Phase 3 trials

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Introduction: Tofacitinib is an oral Janus kinase inhibitor that is being investigated for psoriasis.

Objectives: To assess tofacitinib efficacy, safety and patient-reported outcomes (PRO) in patients (pts) with moderate to severe plaque psoriasis up to 52 weeks.

Methods: Data were pooled across two identical Phase 3 studies: OPT Pivotal 1 and 2 (NCT01276639, NCT01309737). Pts were randomised to tofacitinib 5 mg ($n=746$), 10 mg ($n=742$) or placebo ($n=373$), BID. At Week 16, placebo pts were re-randomised to tofacitinib. Pts not achieving ⩾75% reduction in Psoriasis Area and Severity Index (PASI75) or Physician's Global Assessment of 'clear/almost clear' (PGA response) at Week 28 were withdrawn. Assessments included the proportions of pts achieving PASI75, PGA response, Dermatology Life Quality Index (DLQI) ⩽1 (little/no effect of psoriasis on health-related quality of life), and Itch Severity Item (ISI) ⩽1 (little/no pruritus). Incidence rates (IR, pts with event/100 pt-years) are reported for selected adverse events (AEs).

Results: At Week 16, the proportions of pts achieving PASI75 and PGA responses with tofacitinib 5 mg were 43% and 44%, respectively, and with 10 mg BID 59% for both. PASI75 and PGA responses were maintained up to Week 52 in 74% and 62% of pts with tofacitinib 5 mg BID, and 79% and 72% with 10 mg BID. At Week 16, among pts with baseline DLQI >1, 28% and 44% achieved DLQI ⩽1 with tofacitinib 5 and 10 mg BID, respectively, and among pts with baseline ISI >1, 43% and 61% achieved ISI ⩽1. Serious AEs and discontinuations due to AEs were both reported in <6% of pts with each dose. Five pts died. With tofacitinib 5 and 10 mg BID, IRs (95% confidence interval) were 1.78 (0.89, 3.19) and 2.73 (1.62, 4.32) for serious infections, 1.46 (0.67, 2.77) and 0.61 (0.17, 1.55) for malignancies (excluding non-melanoma skin cancer), and 0.49 (0.10, 1.42) and 0.30 (0.04, 1.09) for cardiovascular events.

Conclusions: Oral tofacitinib demonstrated sustained, dose-dependent efficacy and PRO improvements in pts with moderate to severe psoriasis over 52 weeks. Serious AEs were infrequent and no unexpected safety findings were observed.

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P040

Herpes zoster and tofacitinib therapy in patients with psoriasis

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Introduction: Recent registry data suggest herpes zoster (HZ) events increase with psoriasis therapy. Tofacitinib is an oral JAK inhibitor that is being investigated for psoriasis.

Objective: To assess HZ risk in pts with psoriasis using tofacitinib.

Methods: We identified HZ cases reported by investigators from Phase 2, 3 and long-term extension (LTE) clinical trials (3623 pts exposed to tofacitinib). An independent committee adjudicated cases as multidermatomal (non-adjacent or >2 adjacent dermatomes) or disseminated. We calculated HZ crude incidence rates (IR) as pts with event per 100 pt-years [95% confidence interval (CI)] stratified by baseline demographics and other factors. Potential HZ risk factors were assessed by Cox-proportional hazard models.

Results: 130 (3.6%) pts developed HZ, of which 40 (31%) were female, median age 52 years (range 21–73). Nine (7%) led to hospitalisation. Eight (6%) were multidermatomal; no encephalitis or visceral involvement, or deaths, occurred. Of HZ cases, 104 (80.0%) received antiviral therapy and 121 (93%) continued or resumed tofacitinib after the event. Overall HZ IR was 2.55 (2.13–3.03); IR was highest in older pts, Asians (due to high rates in Japanese pts) and pts using tofacitinib 10 mg BID (Tables). Risk factors included being Asian [hazard ratio (HR) 4.05 (95% CI 2.68–6.11)], tofacitinib 10 mg BID [HR 1.88 (95% CI 1.12–3.15)] and prior biologics [HR 1.78 (95% CI 1.22–2.61)].

Conclusions: In tofacitinib-treated pts, complicated HZ was infrequent. Increased HZ IRs occurred in pts who were older, Asian or with higher tofacitinib dose. Further research is needed to assess the higher risk in Asian (Japanese) pts.

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[P040] Table 1. Crude IR in psoriasis pts with tofacitinib from Phase 2, 3, LTE trials

1-year Phase 3	5 mg BID, n/N	5 mg BID, IR (95% CI)	10 mg BID, n/N	10 mg BID, IR (95% CI)
Age, 45-<65	7/573	1.84 (0.74–3.79)	13/580	3.21 (1.71–5.49)
Age, ⩾65	1/78	1.90 (0.05–10.60)	1/74	1.75 (0.04–9.74)
White	5/1041	0.73 (0.24–1.71)	17/1039	2.31 (1.35–3.70)
Asian	1/89	1.78 (0.05–9.93)	3/92	4.76 (0.98–13.90)

[P040] Table 2

Overall exposure	n/N	IR (95% CI)
Age, 45-<65	79/1668	3.26 (2.58–4.06)
Age, ⩾65	12/219	4.14 (2.14–7.23)
White	97/3108	2.22 (1.80–2.70)
Asian	23/248	5.75 (3.65–8.63)

P041

Efficacy and adverse effects of phototherapy in childhood population

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Introduction: Narrowband phototherapy is an effective and useful treatment for many dermatoses in adults, but there is not a lot of evidence for this use in children.

Objective: Report our experience with children treated with Narrowband phototherapy at the University Hospital Son Espases during the last 8 years.

Material and Methods: We made a retrospective analysis of children aged under 18 years old who had been treated with phototherapy between years 2008 and 2014.

Results: Seventeen children aged between 11 to 18 years old with photoresponsive dermatoses were treated with narrowband ultraviolet (UVB tl01) phototherapy. Seven children had psoriasis, three had vitiligo, two had atopic dermatitis, two had pityriasis lichenoides, one had lichen planus, one had solar urticarial and another one had Schambergs purpura. Patients with psoriasis, pityriasis lichenoides, liquen planus and Schambergs purpura cleared completely, except for one child with psoriasis guttata who didn't show any improvement. Two of the three patients with vitiligo had more than half of repigmentation. Patients with atopic dermatitis had a partial response with a reduction of the area of eczema and a disappearance of the pruritus. There was no response in the patient with solar urticaria. Treatment was well tolerated and no serious effects were reported.

Conclusions: It appears that UVBtl01 phototherapy is a valuable, safe and effective tool that can be used for photoresponsive dermatoses in children.

Disclosure of Interest: None to declare.

P042

Analysis of non-melanoma skin cancer across the tofacitinib rheumatoid arthritis clinical programme

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Introduction: Tofacitinib is an oral Janus kinase inhibitor for the treatment of rheumatoid arthritis (RA).

Objectives: To assess incidence rates (IRs) of non-melanoma skin cancer (NMSC) in Phase (P) 1, 2, 3, and open-label long-term extension (LTE) studies in RA.

Methods: Data (cut-off: 30 August 2013) were pooled from two P1, eight P2, six P3, and two LTE studies; LTE studies ongoing (database not locked). Patients (pts) in P1, P3 and LTE studies received tofacitinib 5 or 10 mg twice daily (BID) as monotherapy or with background disease-modifying antirheumatic drugs (DMARDs). Pts in P2 studies received tofacitinib 1–30 mg BID or 20 mg once daily. IRs (pts with event/100 pt-years [py] of exposure) for first new NMSC were calculated. Overall IR (95% CI) and IRs for selected subgroups are presented.

Results: 6,092 pts (15103 py exposure) received tofacitinib; ⩾1 NMSC occurred in 83 pts (squamous cell carcinoma [SCC] in 39 pts, basal cell carcinoma [BCC] in 52 pts). Five pts had a history of NMSC prior to tofacitinib versus 78 pts who did not. The overall NMSC IR in P1, P2, P3 and LTE was 0.55 (0.45, 0.69); IRs for SCC and BCC were 0.26 (0.19, 0.35) and 0.35 (0.26, 0.45). The IRs for pts from P1/2/3 and LTE with tofacitinib 5 mg BID were 0.61 (0.34, 1.10) and 0.41 (0.26, 0.66), respectively; with tofacitinib 10 mg BID, the IRs were 0.47 (0.24, 0.90) and 0.79 (0.60, 1.05). NMSC IRs were higher in pts previously treated with tumour necrosis factor inhibitor (TNFi; 1.01 [0.67, 1.51]) versus TNFi-naïve pts (0.47 [0.37, 0.61]). Pts ⩾65 years old had higher NMSC IR (1.67 [1.19, 2.35]) versus pts <65 years old (0.38 [0.29, 0.51]). White pts had the highest NMSC IR versus Asian, Black or Other pts (0.86 versus 0.03, 0.00, or 0.14).

Conclusions: NMSC IRs with tofacitinib in the clinical development programme remained stable over time. NMSC IRs appeared consistent with published estimates in pts with RA receiving TNFi (IR 0.22–0.66).[1] Previously presented,[2] reproduced with permission.

Disclosure of Interest: J. R. Curtis Grant/Research support from: Pfizer Inc; E. B. Lee Consultant of: Pfizer Inc; G. Martin Consultant of: Pfizer Inc; X. Mariette Grant/Research support from: Pfizer Inc; K. K. Terry Shareholder of: Pfizer Inc, Employee of: Pfizer Inc; Y. Chen Shareholder of: Pfizer Inc, Employee of: Pfizer Inc; J. Geier Shareholder of: Pfizer Inc, Employee of: Pfizer Inc; J. Andrews Shareholder of: Pfizer Inc, Employee of: Pfizer Inc; M. Kaur Shareholder of: Pfizer Inc, Employee of: Pfizer Inc; H. Fan Shareholder of: Pfizer Inc, Employee of: Pfizer Inc; C. Nduaka Shareholder of: Pfizer Inc, Employee of: Pfizer Inc.

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P043

Integrated safety analysis of tofacitinib in RA clinical trials with a cumulative exposure of 12664 patient-years

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Introduction: Tofacitinib is an oral Janus kinase inhibitor for the treatment of rheumatoid arthritis (RA). Phase (P) 2, P3 and long-term extension (LTE) studies described the tofacitinib safety profile in RA.

Objectives: To describe tofacitinib safety data in patients (pts) from these studies, focusing on safety events of special interest over time.

Methods: Pts received ⩾1 dose of tofacitinib (doses pooled), as monotherapy or with background disease-modifying antirheumatic drugs, in 6 P2, 6 P3 and 2 LTE studies (ongoing; database not locked) up to 10 April 2013. Incidence rates (IR; pts with events/100 patient-years [py] and 95% confidence intervals [CI]) are listed.

Results: 5,671 pts were included (12664 py of tofacitinib exposure, median exposure 2.4 years); 4,204 (74%), 3,804 (54%), 1,948 (34%) and 555 (10%) received tofacitinib for ⩾12, ⩾24, ⩾36 and >48 months (mo), respectively; 926 (16.3%) discontinued due to adverse events (AEs). The IR of mortality was 0.3 (0.2–0.4). IRs for serious AEs (SAEs) and AEs of interest were consistent over time (Tables). IRs for opportunistic infections, tuberculosis and herpes zoster (HZ) were 0.3 (0.2, 0.4), 0.2 (0.1, 0.3) and 4.2 (3.9, 4.6). For HZ, 93% were non-serious; disseminated and multidermatomal cases were rare. Overall IR of major adverse cardiovascular events was 0.5 (0.3, 0.6) and IRs were similar over time.

Conclusions: The rates of SAEs and AEs of special interest were stable across time intervals; no new risks were identified.

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[P043] Table 1

IR (95% CI)	0–6 mo	6–12 mo	12–18 mo	18–24 mo
SAE	10.8 (9.6–12.1)	10.4 (9.2–11.9)	12.1 (10.6–13.8)	10.4 (8.9–12.2)
Serious infections (SI)	2.6 (2.0–3.3)	3.4 (2.7–4.3)	3.2 (2.5–4.1)	3.2 (2.4–4.2)
HZ (serious & non-serious)	4.2 (3.5–5.1)	4.7 (3.9–5.7)	4.2 (3.4–5.3)	4.4 (3.5–5.6)
Malignancy excluding NMSC	0.7 (0.4–1.1)	0.7 (0.4–1.1)	0.9 (0.6–1.5)	1.0 (0.6–1.7)

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[P043] Table 2

IR (95% CI)	24–30 mo	30–36 mo	36–42 mo	>42 mo
SAE	10.0 (8.4–11.9)	8.5 (6.9–10.4)	7.3 (5.5–9.8)	8.8 (6.9–11.3)
SI	2.9 (2.2–4.0)	2.9 (2.0–4.0)	2.8 (1.8–4.3)	1.9 (1.2–3.1)
HZ (serious & non-serious)	4.0 (3.1–5.2)	5.1 (3.9–6.6)	3.9 (2.6–5.7)	2.1 (1.3–3.4)
Malignancy excluding NMSC	0.8 (0.5–1.5)	1.0 (0.6–1.8)	0.8 (0.4–1.8)	1.0 (0.5–2.0)

P044

Persistence of biologic therapy in psoriatic disease: Results from the Psoriasis Longitudinal Assessment and Registry (PSOLAR)

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Objective: To evaluate persistency of biologic use in pts with PsO & PsA.

Methods: PSOLAR evaluates outcomes for PsO pts eligible to receive tx with systemic agents. Among PSOLAR pts,36%($n=4,317$) have self-reported PsA. Duration of tx was defined as time(days)between first dose of biologic & first of:1) discon 2) switch 3) registry withdrawal or 4) last data cut (Aug 23, 2013). Separate analyses were performed for:1st line (bio-naïve),2nd line,& 3rd line usage to reduce confounding associated with prior exposures for overall & PsA pop. Persistence was assessed by Kaplan-Meier analysis for time to tx stop/switch separately for ustekinumab (UST),infliximab (IFX),adalimumab (ADA),& etanercept (ETN).Cox proportional hazard regression analysis compared time to stop/switch of UST with other biologics for each cohort.

Results: Most starts were attributed to UST(1,833 pts) & ADA (1,303)with fewer starts for ETN (537) & IFX (327).Among UST starts, the proportions of 1st, 2nd & 3rd line usage were 20%, 31%, & 30%; ADA starts 31%, 48%, & 15%; ETN starts 54%, 29% & 13%; IFX starts 19%, 28% & 32%, respect. Baseline clinical characteristics were generally comparable across biologics & cohorts. Fewer pts discon UST than IFX, ETN, & ADA in all 3 lines. Median duration of tx was generally longer for UST versus anti-TNF txs. For 1st line starts, better persistence was observed for UST based on sig differences in time to stop/switch for each biologic versus UST(IFX versus UST:HR3.04;CI:1.66–5.57;$P=0.0003$;ADAvsUST:HR4.99;CI:3.39–7.35;$P<0.0001$;ETNvsUST:HR5.59;CI:3.77–8.29;$P<0.0001$).Similar results were observed for 2nd & 3rd line starts. In the subgrp with self-reported PsA, for 1st line starts, better persistence was observed with UST versus ETN(HR 2.53;CI 1.39–4.62;$P=0.0024$);no sig differences were seen for UST versus IFX & ADA. UST had better persistence versus anti-TNFs in the analyses of 2nd & 3rd line starts. Reasons for stop/switch were similar across biologics & cohorts. Data were not adjusted for differences among cohorts, eg MTX use, insurance, administration, setting, & region.

Conclusion: Persistence of UST tx in psoriatic disease was sig better than anti-TNF txs in biologic-naïve & experienced pts, with lower rates of stopping/switching&higher median days on tx.

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P045

Efficacy and safety of ustekinumab in psoriatic arthritis patients with spondylitis and peripheral joint involvement: Results from 2 phase 3, multicenter, double-blind, placebo-controlled study

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Objectives: To evaluate UST in a subgrp of PsA pts with physician diagnosed spondylitis & peripheral joint involvement(PJI) from PSUMMIT 1 & 2.

Methods: Adult PsA pts with active disease were rand to UST45 mg, 90 mg, or PBO at wks 0,4, & q12wks, thereafter. PBO pts crossed over to UST45 mg at wks 24 & 28 followed by q12wk dosing. At wk16, pts with <5% improvement in TJC & SJC entered blinded early escape. No concomitant DMARDs except for MTX were permitted.

Results: 256 (28% of PSUMMIT 1 & 2 pop) rand pts(92 PBO, 164 UST combined) had spondylitis with PJI at baseline; clinical efficacy & radiographic progression(see table). Sig more UST-tx pts achieved BASDAI20/50/70 responses versus PBO at wk24 (54.8%/29.3%/15.3% versus 32.9%/11.4%/0%). During the PBO-controlled period, AE rates were numerically higher in PBO versus combined UST-tx grps (AEs 41.3% versus 34.8%; SAEs 2.2% versus 1.2%; discon due to AEs 3.3% versus 0.6%; infections 16.3% versus 13.4%).Thru 1yr, safety was consistent with the overall PsA pop.

Conclusion: UST sig improved signs & symptoms & radiographic progression versus PBO thru wk24; efficacy was maintained thru wk52.UST was well-tolerated & demonstrated a safety profile similar to the overall PsA study pop.

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[P045] Table 1. PSUMMIT 1 and 2-Efficacy Outcomes in Patients with Spondylitis and Peripheral Joint Involvement at Baseline (BL)

	Wk 24		Wk 52	
	PBO 92	UST Combined 164	PBO→ 45 mg 81	UST Combined 156
ACR20 /ACR50/ACR70 (%)	$N=92$ 22.8/3.3/1.1	$N=164$ 43.9^/ 25.6/11.0 ^$P=0.001$	$N=81$ 65.4/39.5/16.0	$N=156$ 62.8/ 34.6/19.2
Mean % change (median) from BL entheses score (MASES index)*	$N=63$ −16.01 (−26.67)	$N=132$ −46.66 (−50.00) $P=0.017$	$N=60$ −53.06 (−87.50)	$N=127$ −54.76 (−73.33)
Mean % change(median) from BL dactylitis score**	$N=41$ −11.03 (0.00)	$N=83$ −57.48 (−88.89) $P<0.001$	$N=39$ −69.76 (−100.00)	$N=82$ −68.94 (−100.00)
Mean (SD) change from BL HAQ-DI	$N=92$ −0.11 (0.39)	$N=164$ −0.33(0.53) $P<0.001$	$N=81$ −0.39 (0.42)	$N=156$ −0.37(0.55)
PASI 75 response***	$N=69$ 11.6%	$N=137$ 63.5% $P<0.001$	$N=61$ 65.6%	$N=129$ 70.5%
Total vdH-S mean change from BL (peripheral joints)	1.51 (6.41)	0.00(1.69) $P=0.003$	3.04 (11.86)	0.25 (2.13)

Pts who did not receive UST excluded. ^ACR20 only, *enthesitis and dactylitis **with spondylitis and peripheral joint involvement(PJI) at BL; *** pts with >3% BSA psoriasis involvement with spondylitis & PJI at BL.

P046

The prediction and benefits of minimal disease activity in patients with psoriatic arthritis in ADEPT trial

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Introduction: Minimal disease activity (MDA) is a clinically relevant treatment target for psoriatic arthritis (PsA).

Objective: To determine if baseline (BL) disease activity and/or patient (pt) demographics predict achieving MDA at Wk12 in pts with PsA. To evaluate pt-reported outcomes (PRO) at Wk24 associated with achieving MDA.

Methods: Data were from ADEPT (NCT00646386) trial of adalimumab v PBO in pts with PsA. BL variables predicting achieving Wk12 MDA were identified by univariate (UVA) and multivariate (MVA) analyses: age, weight, modified total Sharp score, tender/swollen joint count, Pt Global Assessment of pain (PGA-p) or disease activity, Physician's GA of Disease or Psoriasis, Health Assessment Questionnaire (HAQ), dactylitis, enthesitis (Ent), PASI, sex, smoking/alcohol/MTX use, Rh factor (+/-), investigator-reported spondylitis, CRP (</⩾2.87), and Ps/PsA duration (</⩾5 yr). Pts achieving MDA or not at Wk24 were termed achievers and non-achievers (NA) respectively. Wk24 PROs were assessed (Table).

Results: In UVA, lower BL scores for PGA-p, SJC66, TJC68, Ent and HAQ predicted Wk12 MDA. In MVA, a 1-unit increase in BL HAQ and Ent score reduced odds of Wk12 MDA by 37.6% and 16.0% respectively. Odds of achieving MDA was reduced by 22.6% for pts with spondylitis at BL compared to pts without. At Wk24, achievers ($n=27$) had significantly better scores ($P<0.01$) for all PRO than NA ($n=98$) (Table). Achievers had favorable BL scores for SF-36 total, PCS and FACIT-F, but not MCS or DLQI; larger changes from BL than NA and reached MCID for all PRO; NA reached MCID only for SF-36 PCS. Age, sex, PsA duration and MTX use did not influence PRO.

Conclusion: Absence of spondylitis and lower scores for HAQ and Ent at BL were found to increase likelihood of Wk12 MDA achievement. MDA achievement at Wk24 was associated with clinically important improvement in quality of life and fatigue.

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[P046] Table 1. Wk24 PROs

	Achievers ($n=27$)	NA ($n=98$)
Total SF-36[1a]	65.3 ± 13.4	41.7 ± 17.0
PCS[b]	51.0 ± 7.2	35.0 ± 10.8
MCS[b]	53.2 ± 11.4	45.9 ± 10.7
Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F)[c]	43.5 ± 10.6	30.5 ± 12.2
DLQI[a]	2.1 ± 5.4	6.9 ± 6.8

[1]Minimum clinically important differences (MCID):[a]⩾5;[b]⩾2.5;[c]⩾4.

P047

Multiple imputation methodology is reflective of secukinumab efficacy in real clinical practice: Data from the FIXTURE and ERASURE studies in moderate to severe plaque psoriasis

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Introduction: Missing efficacy data are inevitable in long-term clinical trials, and an array of different statistical methodologies is available to deal with this problem. However, the methodology selected affects the interpretation of results.[1]

Objective: To assess the effect that different data imputation methods have on the analysis of efficacy in two 52 Wk phase 3 trials (ERASURE and FIXTURE).

Methods: Per study protocols,[2] secukinumab 300 mg, 150 mg and etanercept 50 mg (FIXTURE only) were evaluated in moderate to severe plaque psoriasis, and missing efficacy data were imputed using non-responder imputation (NRI), whereby all missing data are classified as non-response. Subjects with ⩾90% improvement in baseline PASI 90 score were reanalyzed using other imputation methods: observed data (only subjects with observed data at endpoints are included), last observation carried forward (LOCF; imputation with last available response for a subject), and multiple imputation (MI; missing data is replaced with multiple values representing an overall distribution of possible data).

Results: The observed data method resulted in the highest estimates of PASI 90 responders at Wk 52 (Tables 1 and 2). PASI 90 rates were similar using LOCF and MI. The proportion of PASI 90 responders using NRI was consistently numerically lower compared with the other methodologies.

Conclusions: Different data imputation methodologies produced divergent estimates of secukinumab efficacy, with per protocol NRI consistently yielding the lowest estimates. Stringent assumption of non-response for all missing data is not reflective of real clinical practice and is likely less accurate than MI for estimating the true response rate.

Disclosure of Interest: R. Langley Consultant of: AbbVie, Amgen, Celgene, Janssen, LEO Pharma, Merck, Novartis, and Pfizer; K. Reich Consultant of: AbbVie, Amgen, Biogen-Idec, Celgene, Centocor, Covagen, Forward Pharma, GlaxoSmithKline, Janssen-Cilag, Leo, Lilly, Medac, MSD, Novartis, Pfizer, Takeda, and Vertex; C. Papavassilis Employee of: Novartis; T. Fox Employee of: Novartis; Y. Gong Employee of: Novartis; A. Guettner Employee of: Novartis.

References:

1. Langley *et al. Br J Dermatol* 2013;169:1198–1206.
2. Langley *et al., N Engl J Med* 2014; 371:326–8.

[P047] Table 1. PASI 90 Responders (%) at Wk 52 (ERASURE)

	NRI	Observed	LOCF	MI
Secukinumab 300 mg	60.0	68.7	66.9	65.4
Secukinumab 150 mg	36.2	44.2	43.6	42.2

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[P047] Table 2. PASI 90 Responders (%) at Wk 52 (FIXTURE)

	NRI	Observed	LOCF	MI
Secukinumab 300 mg	65.0	74.2	71.2	70.6
Secukinumab 150 mg	45.0	54.2	49.8	49.3
Etanercept	33.4	42.5	39.0	39.0

P048

Efficacy and safety of itolizumab in severe refractory plaque type psoriasis

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Background: Itolizumab, a humanized monoclonal antibody to CD6, is a novel therapeutic agent recently reported to be useful in treatment of moderate to severe chronic plaque psoriasis.[1]

Objective: To evaluate the long-term efficacy and safety of itolizumab (1.6 mg/kg) in psoriasis patients having severe refractory plaque type disease.

Methods: Eleven patients with severe refractory plaque type psoriasis were treated with itolizumab 1.6 mg/kg IV every 2 weeks for 12 weeks, followed by once a month infusion for next 3 months and thereafter once in 3 months for up to 12 months. The primary endpoint was the proportion of patients with at least 75% improvement in PASI at week 12 (PASI75). Those with partial response (PASI⩾50 but <75) at week 28 were maintained on 6 weekly infusion till they achieved PASI 75. Response to treatment was evaluated by PASI scoring and adverse effects during infusions and thereafter was recorded.

Results: At week 12, 54.5% (6 out of 11) patients met PASI75 whereas remaining 5 patients had partial response (PASI>50). At the end of 28th week, 8 patients had achieved PASI75. Of these, 3 patients had achieved PASI 90 at 28 week. A further improvement was observed in patients receiving the itolizumab maintenance infusions resulting in PASI100 in 1 patient. Three patients who could not achieve PASI 75 at 28 week were continued on 6 weekly infusions. Two of these 3 patients met PASI 75 at 12 months. Infusion-related reactions after first dose (12.6% of patients) were the most frequent adverse events, reduced sharply thereafter. No serious adverse effect was observed during 12 months treatment period. Main limitation of this study was absence of placebo or control group.

Conclusions: Itolizumab is an effective and well-tolerated new biological therapy for patients with severe refractory plaque psoriasis.

Disclosure of Interest: None to declare.

References:

1. Krupashankar DS, Dogra S, Kura M, Saraswat A, Budamakuntla L, Sumathy TK *et al.* Efficacy and safety of itolizumab, a novel anti-CD6 monoclonal antibody, in patients with moderate to severe chronic plaque psoriasis: Results of a double-blind, randomized, placebo-controlled, phase-III study. *J Am Acad Dermatol,* 2014; 7:484–2.

P049

Secukinumab administration by pre-filled syringe maintains efficacy in moderate to severe plaque psoriasis over 52 weeks: results of the FEATURE trial

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Introduction: Sustaining treatment benefits is important in plaque psoriasis. Secukinumab, a fully human anti–IL-17A monoclonal antibody, has been demonstrated to be highly efficacious in the treatment of moderate to severe psoriasis, starting at early time points, with a sustained effect and a favorable safety profile.[1]

Objectives: The Phase 3 FEATURE study examined secukinumab efficacy and safety when self-administered using a pre-filled syringe (PFS).

Methods: Subjects were randomized 1:1:1 to secukinumab 300 mg, 150 mg or PBO. Treatments were self-administered using a PFS at Baseline, 1, 2, 3 and 4, then every 4 Wks until Wk 12 (PBO) or secukinumab extension phase end (Wk 208). Co-primary endpoints were secukinumab PASI 75 and IGA mod 2011 0/1 response rates at Wk 12 compared to placebo. Secondary endpoints included PASI 90, PASI 100 and PFS acceptability, rated using the Self-Injection Assessment Questionnaire (SIAQ). Wk 52 efficacy analyses were performed using multiple imputation on data from 58 subjects receiving 300 mg secukinumab and 59 subjects receiving 150 mg secukinumab.

Results: Secukinumab was superior to PBO at Wk 12 as reported previously.[2] Peak efficacy was observed from Wk 16 in both groups (PASI 75 achieved in 90.4% and PASI 90 in 78.7% of subjects receiving 300 mg). At Wk 52, PASI 75 response for 83.5% of subjects with secukinumab 300 mg and 63.5% receiving secukinumab 150 mg. IGA mod 2011 0/1 rates were 71.5% and 43.6% for secukinumab 300 mg and 150 mg. 68% and 50.3% of subjects had PASI 90 with secukinumab 300 mg and 150 mg, respectively. PASI 100 was recorded for 47.5% of subjects with secukinumab 300 mg and 31.1% with 150 mg secukinumab at Wk 52. No new or unexpected safety signals were observed to Week 52. SIAQ-rated user satisfaction with the PFS remained high over this period.

Conclusions: Long-term administration of secukinumab by PFS is effective in maintaining reductions in PASI score up to 52 wks, including substantial PASI 90 and PASI 100 responses.

Disclosure of Interest: J.C. Prinz Consultant of: Biogen-Idec (formerly Biogen), Novartis, Wyeth, Pfizer, Merck-Serono (formerly Serono), Essex pharma, MSD, Galderma, Centocor, Abbott, Janssen-Cilag/Janssen-Ortho; A. Blauvelt Consultant of: AbbVie, Amgen, Boehringer Ingelheim, Celgene, Janssen, Lilly, Merck, Novartis, Pfizer, and Sandoz; A. Gottlieb Grant/Research support from: (Paid to Tufts Medical Center) Centocor (Janssen), Amgen, Abbott (Abbvie), Novartis, Celgene, Pfizer, Lilly, Coronado and Levia, Consultant of: Amgen Inc., Astellas, Centocor (Janssen), Inc., Celgene Corp., Bristol Myers Squibb Co., Beiersdorf, Inc., Abbott Labs. (Abbvie), TEVA, Actelion, UCB, Novo Nordisk, Novartis, Dermipsor Ltd., Incyte, Pfizer, Canfite, Lilly, Coronado, Vertex, Karyopharm, CSL Behring Biotherapies for Life and Glaxo Smith Kline; R. You Shareholder of: Novartis, Employee of: Novartis; T. Fox Employee of: Novartis.

References:

1. Langley *et al., N Engl J Med.* 2014; 371:326–38.
2. Blauvelt *et al., Br J Dermatol.* 2015; 172:484–93.

P050

Secukinumab administration by autoinjector maintains efficacy in moderate to severe plaque psoriasis over 52 weeks: results of the JUNCTURE trial

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Introduction: Sustained, long-term benefit is important in plaque psoriasis treatment. Secukinumab, a fully human anti–IL-17A monoclonal antibody, has been demonstrated to be highly efficacious in the treatment of moderate to severe psoriasis, starting at early time points, with a sustained effect and a favorable safety profile.[1]

Objectives: Secukinumab efficacy and safety when self-administered using an autoinjector were examined in the Phase 3 JUNCTURE study.

Methods: Subjects were randomized 1:1:1 to secukinumab 300 mg, 150 mg or PBO. Treatments were self-administered using an autoinjector at Baseline, 1, 2, 3 and 4, then every 4 wks until Wk 12 (PBO) or secukinumab extension phase end (Wk 208). Co-primary endpoints were secukinumab efficacy compared to PBO for PASI 75 and IGA mod 2011 0/1 response rates at Wk 12. Secondary endpoints included PASI 90, PASI 100 and autoinjector acceptability, rated using the Self-Injection Assessment Questionnaire (SIAQ). Wk 52 data from 60 subjects in each secukinumab dose group were analysed using multiple imputation.

Results: Secukinumab was superior to PBO at Wk 12 as reported previously.[2] Peak efficacy was observed from Wk 16 (PASI 75 achieved in 93.3% and PASI 90 in 79.8% of subjects receiving 300 mg). At Wk 52, PASI 75 response was 81.4% for subjects treated with secukinumab 300 mg and 75.2% for secukinumab 150 mg. PASI 90 was achieved at Wk 52 by 64.1% and 57.4% of subjects receiving secukinumab 300 mg and 150 mg, respectively. PASI 100 was reported for 38.8% of subjects with 300 mg secukinumab and 33.1% of subjects with 150 mg at Wk 52. In subjects receiving secukinumab 300 mg and 150 mg, Wk 52 IGA mod 2011 0/1 was reported at 69.6% and 60.2%, respectively. No new or unexpected safety signals were observed to Wk 52. Satisfaction with the autoinjector (SIAQ-rated) remained high over this period.

Conclusions: Long-term reductions in PASI score up to 52 wks were achieved with secukinumab self-administration with an autoinjector, with substantial PASI 90 and PASI 100 response rates.

Disclosure of Interest: C. Paul Consultant of: AbbVie Pharmaceuticals, Amgen, Celgene Corporation, Eli Lilly and Company, Janssen Pharmaceuticals, LEO Pharma, Pfizer Inc, Pierre Fabre; J.-P. Lacour Grant/Research support from: Novartis; R. You Employee of: Novartis; T. Fox Employee of: Novartis.

References:

1. Langley *et al., N Engl J Med* 2014; 371:326–38.
2. Paul C *et al., J Eur Acad Dermatol Venereol* 2014; Sep 22 [Epub].

P051

Secukinumab demonstrates an acceptable safety profile in moderate to severe plaque psoriasis: Pooled analysis of 10 phase 2/3 studies

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Introduction: Secukinumab, a fully human anti–IL-17A mAb, has shown strong and sustained efficacy in psoriasis.

Objectives: We conducted a pooled safety analysis of 3,993 psoriasis subjects from 10 phase 2/3 secukinumab studies.

Methods: All subjects received s.c. secukinumab 300 mg, 150 mg, placebo (PBO), other doses (not listed in abstract), or etanercept (ETN) 50 mg in one study. Adverse events (AEs), and AEs of Interest (infections, candidiasis, neutropenia, Crohn's disease [CD], ulcerative colitis, [UC], malignancy, major adverse cardiovascular events [MACE]) were analyzed at Wk 12 and Wk 52.

Results: AE rates with secukinumab 300 mg (54.2%) and 150 mg (56.3%) at Wk 12 were numerically higher versus PBO (50.4%) and comparable to ETN (57.6%). The slight imbalance versus PBO was mainly due to non-serious infections. At Wk 52, exposure-adjusted incidence rates (IR per 100 subject-years) of AEs with secukinumab 300 mg (236.1; $n=1,410$) and 150 mg (239.9; $n=1,395$) were lower versus PBO (351.8; $n=793$) and comparable to ETN (243.4; $n=323$). IR of infections showed a similar trend, while IRs of serious AEs and serious infections were comparable across all treatments (Table 1). The IR of non-serious, mild/moderate, localized skin/mucosal candidiasis was higher with secukinumab 300 mg (Table 1). There was one death (hemorrhagic stroke [150 mg]), unrelated to treatment as judged by the investigator. Neutropenia was infrequent (Grade 3, $n=18$ for any secukinumab dose; no Grade 4 cases), mild, transient, not associated with serious infections and did not lead to discontinuations. No clinically meaningful difference was found in IRs of MACE, CD, UC and malignancy (Table 2).

Conclusions: This analysis of pooled safety data from 10 secukinumab studies supports a favorable safety profile of secukinumab over 52 wks in subjects with moderate to severe psoriasis, although more data are needed to make definitive conclusions for MACE, CD, UC and malignancy.

Disclosure of Interest: C. Griffiths Grant/Research support from: AbbVie, Actelion, Biotest, Celgene, GSK-Stiefel, Incyte, Janssen, LEO Pharma, Merck Sharp & Dohme, Novartis, Pfizer, Trident, and UCB, Consultant of: AbbVie, Actelion, Biotest, Celgene, GSK-Stiefel, Incyte, Janssen, LEO Pharma, Merck Sharp & Dohme, Novartis, Pfizer, Trident, and UCB; K. Reich Consultant of: AbbVie, Amgen, Biogen-Idec, Celgene, Centocor, Covagen, Forward Pharma, GlaxoSmithKline, Janssen-Cilag, Leo, Lilly, Medac, MSD, Novartis, Pfizer, Takeda, and Vertex, Speakers bureau of: AbbVie, Amgen, Biogen-Idec, Celgene, Centocor, Covagen, Forward Pharma, GlaxoSmithKline, Janssen-Cilag, Leo, Lilly, Medac, MSD, Novartis, Pfizer, Takeda, and Vertex; C. Leonardi Consultant of: AbbVie, Amgen, Celgene, Dermira, Eli Lilly, Galderma, Janssen, Leo Pharma, Merck, Novartis, Pfizer, Sandoz, Stiefel, and UCB, Speakers bureau of: AbbVie, Amgen, Celgene, Dermira, Eli Lilly, Galderma, Janssen, Leo Pharma, Merck, Novartis, Pfizer, Sandoz, Stiefel, and UCB; A. Blauvelt Consultant of: AbbVie, Amgen, Boehringer Ingelheim, Celgene, Janssen, Lilly, Merck, Novartis, Pfizer, and Sandoz; N. Mehta Employee of: United States government; T.-F. Tsai Consultant of: Abbvie, Celgene, Janssen-Cilag, Leo, Lilly, Galderma, Novartis, Pfizer, Speakers bureau of: Abbvie, Celgene, Janssen-Cilag, Leo, Lilly, Galderma, Novartis, Pfizer; Y. Gong Employee of: Novartis Pharma AG; J. Huang Employee of: Novartis Pharma AG; T. Fox Employee of: Novartis Pharma AG.

[P051] Table 1

Table 1—IR Wk 52	300 mg	150 mg	PBO	ETN
Infections	91.1	85.3	101.9	93.7
Serious AEs	7.4	6.8	7.5	7.0
Serious infections	1.4	1.1	1.0	1.4
Candidiasis	3.6	1.9	1.0	1.4

[P051] Table 2

Table 2—IR Wk 52	300 mg	150 mg	PBO	ETN
Malignancy	0.8	1.0	1.5	0.7
CD	0.0	0.2	0.0	0.0
UC	0.2	0.2	0.0	0.3
MACE	0.4	0.4	0.5	0.3

P052

Secukinumab, a novel anti–IL-17A antibody, exhibits low immunogenicity during long-term treatment in subjects with moderate to severe plaque psoriasis

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Introduction: The proinflammatory cytokine interleukin (IL)-17A is pivotal in psoriasis pathogenesis. Secukinumab, a fully human monoclonal antibody (mAb), selectively targets IL-17A and has been demonstrated to be highly efficacious in the treatment of moderate to severe psoriasis, starting at early time points, with a sustained effect and a favorable safety profile. mAb therapies can induce anti-drug antibodies (ADA) that may affect pharmacokinetics, diminish response or cause hypersensitivity.

Objectives: This study evaluates the immunogenicity of secukinumab across phase 3 trials.

Methods: Blood samples were analyzed at Baseline, Wks 12, 24, and 52 from 2,842 plaque psoriasis subjects exposed to secukinumab (most receiving 150 or 300 mg) in six phase 3 studies. Treatment-emergent ADA (TE-ADA) were defined as a positive ADA signal in post-treatment samples from subjects negative at Baseline. Confirmed TE-ADA samples were analyzed for neutralizing potential. The ADA assay can detect 4 ng/ml of a positive control antibody (PCA [secukinumab absent]), or at least 250 ng/ml PCA (<53.8µg/ml secukinumab present).

Results: TE-ADA were detected in 10 subjects from 3 studies with 52-wk exposure with none detected in the remaining studies. TE-ADA rates during secukinumab treatment (300 and 150 mg) were 3/1410 (0.2%) and 7/1395 (0.5%), respectively. No correlations between TE-ADA and secukinumab dose, frequency, or mode of administration were observed. Among 10 subjects with TE-ADA, 5 (50%) later reverted to a seronegative state during therapy. Steady-state secukinumab serum concentrations were <53.8 µg/ml in nearly all Wk 24 and Wk 52 samples. Of the 96 (5%) secukinumab-exposed subjects who had serum sample drug levels >53.8 µg/ml at Wk 52, 97% achieved at least PASI 75, suggesting that ADA, if undetectable due to high serum secukinumab, did not reduce efficacy. Three of 10 subjects with TE-ADA tested positive for neutralizing antibodies; two maintained clinical response up to Wk 52 and one regained response after retreatment.

Conclusions: The TE-ADA rate was low and development of TE-ADA or neutralizing antibodies were not associated with loss of secukinumab efficacy.

Disclosure of Interest: K. Reich Consultant of: AbbVie, Amgen, Biogen-Idec, Celgene, Centocor, Covagen, Forward Pharma, GlaxoSmithKline, Janssen-Cilag, Leo, Lilly, Medac, MSD, Novartis, Pfizer, Takeda, and Vertex; A. Blauvelt Consultant of: AbbVie, Amgen, Boehringer Ingelheim, Celgene, Janssen, Lilly, Merck, Novartis, Pfizer, and Sandoz; A. Armstrong Grant/Research support from: Lilly, Consultant of: AbbVie, Amgen, Janssen, Merck, Lilly and Pfizer; T. Fox Employee of: Novartis; J. Huang Employee of: Novartis; G. Bruin Employee of: Novartis.

P053

Characterization of residual psoriasis in adalimumab-treated PASI90 responders: *post hoc* analysis of REVEAL

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Introduction: Response to psoriasis (PS) treatment may vary by body region.

Objective: To evaluate the location and extent of residual PS plaques among patients who achieved an overall ⩾90% improvement in Psoriasis Area and Severity Index score (PASI90) after treatment with adalimumab (ADA) for 16 weeks. And to better define what constitutes a PASI90 responder to ADA.

Methods: Data were obtained from initial 16-week, double-blind, placebo-controlled treatment period of phase 3 REVEAL study (NCT00237887). A total of 1212 patients with moderate to severe PS were randomized 2:1 to receive 40-mg ADA (after initial 80-mg dose) or placebo every other week. PASI response rates were calculated overall and by the 4 body regions that comprise the PASI (head and neck, trunk, upper extremities, lower extremities). This *post hoc* analysis examined regional PASI responses in patients treated with ADA who achieved an overall PASI90 response at week 16.

Results: Of 814 patients randomized to ADA, 366 (45.0%) achieved an overall PASI90 response at week 16. Of those PASI90 responders, 163 (44.5%) achieved an overall PASI100 response (ie, no residual body surface area [BSA] involvement in any of the 4 anatomic regions). The percentage of PASI90 responders with no residual BSA involvement by anatomic region was as follows: 86.9% for head and neck, 87.2% for trunk, 72.4% for upper extremities, 65.8% for lower extremities. Percentage of overall PASI90 responders with >0% and ⩽10% residual BSA involvement by body region was 10.4% for head and neck, 11.7% for trunk, 26.2% for upper extremities, 31.7% for lower extremities. A total of 6.8% of overall PASI90 responders had more than 10% BSA involvement in any of the 4 body regions examined.

Conclusions: Approximately half of ADA-treated PASI90 responders had no residual involvement in any body region. Anatomic regions least likely to have residual BSA involvement among PASI90 responders were the head and neck and the trunk, while the lower extremities were least likely to achieve full clearance by week 16. The vast majority of PASI90 responders (93.2%) did not have ⩾10% body surface involvement in any of the 4 separate anatomic regions.

Disclosure of Interest: J. Crowley Grant/Research support from: AbbVie, Amgen, Celgene, Lilly, Jansen, Merck, Regeneron, Sandoz, and Maruho, Consultant of: AbbVie, Amgen, and Celgene, Speakers bureau of: AbbVie, Amgen, and Celgene; C. Ryan Consultant of: AbbVie, Lilly, Medimetriks, Xenoport, and Pfizer, Speakers bureau of: AbbVie; Z. Geng Shareholder of: AbbVie, Employee of: AbbVie; M. Okun Shareholder of: AbbVie, Employee of: AbbVie.

P054

Efficacy and safety of adalimumab versus methotrexate treatment in pediatric patients with severe chronic plaque psoriasis: Results from the 16-Week randomized, double-blind period of a phase 3 study

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Introduction: This study (NCT01251614) evaluated safety and efficacy of adalimumab (ADA) v methotrexate (MTX) treatment (Tx) in pediatric patients (pts) with chronic plaque psoriasis.

Objective: Report results from the initial 16-week, double-blind Period (Pd) A of this 4-Pd multi-site international study.

Methods: In PdA, pts were randomized 1:1:1 to initial 0.8mpk ADA up to 40 mg, then every-other-week (eow) from Wk1; initial 0.4mpk ADA up to 20 mg, then eow from Wk1; or 0.1–0.4mpk MTX weekly up to 25 mg/wk. Eligibility included pts aged 4–18 yrs, Physician's Global Assessment (PGA)⩾4 or; body surface area involved >20%; or PASI>20; or PASI>10 plus at least 1 of: active psoriatic arthritis unresponsive to NSAIDS, clinically relevant facial, genital, or hand/foot involvement, or Children's Dermatology Life Quality Index>10. Primary efficacy endpoints, ⩾PASI75 response and PGA clear/minimal (0/1) at Week 16 (ADA- 0.8mpk v MTX), were evaluated for intent-to-treat population; non-responder imputation was applied. Safety was evaluated for pts who received at least 1 dose of study drug (Table).

Results: Of 114 enrolled (MTX $n=37$, ADA-0.4mpk $n=39$, ADA-0.8mpk $n=38$), 57% were female; 90% were white. Mean age was 13.0 yrs (SD 3.76, range 5–18). BMI distribution by age- and sex-adjusted percentiles was 4.4% (<5th, underweight), 59.6% (5th-<85th, normal weight), 14.9% (85th-<95th, overweight), 21.1% (⩾95th, obese). Significantly higher proportion of ADA-0.8 mpk pts achieved PASI75 response at Week 16 (57.9%) v MTX (32.4% [95% CI: −47.2, −3.7] $P=0.027$). Approximately 20% more ADA-0.8mpk pts achieved PGA 0/1 response at Week 16 (60.5%) v MTX (40.5%; [95% CI: −42.2, 2.2] $P=0.083$).

Conclusion: After 16 weeks, adalimumab 0.8mpk eow demonstrated significant and clinically meaningful efficacy outcomes over MTX in this population of pediatric patients with chronic plaque psoriasis. ADA Tx had a similar safety profile to MTX; no new safety risks were identified.

Disclosure of Interest: K. Papp Grant/Research support from: AbbVie, Amgen, Boehringer-Ingelheim, Celgene, Eli Lilly, Janssen, Kyowa, Leo Pharma, Merck (MSD), Novartis, Pfizer, Consultant of: AbbVie, Amgen, Boehringer-Ingelheim, Celgene, Eli Lilly, Janssen, Kyowa, Leo Pharma, Merck (MSD), Novartis, Pfizer; D. Thaci Grant/Research support from: AbbVie, Leo and Pfizer, Consultant of: AbbVie, Amgen, Biogen-Idec, Celgen, Janssen, Leo, Novartis and Pfizer, Speakers bureau of: AbbVie, Amgen, Biogen-Idec, Celgene, Janssen, Leo, Novartis and Pfizer; D. Marcoux Grant/Research support from: AbbVie, Johnson & Johnson, Pierre Fabre and Galderma, Consultant of: AbbVie, Johnson & Johnson, Pierre Fabre and Galderma, Speakers bureau of: AbbVie, Johnson & Johnson, Pierre Fabre and Galderma; L. Weibel Grant/Research support from: AbbVie, Consultant of: Pierre Fabre, Meda, and Pfizer, Speakers bureau of: Pierre Fabre, Meda, and Pfizer; K. Unnebrink Shareholder of: AbbVie, Employee of: AbbVie; D. A. Williams Shareholder of: AbbVie, Employee of: AbbVie.

[P054] Table 1. Treatment emergent adverse events (TEAEs) PdA

	MTX $N=37$ n (%)	ADA-0.4mpk $N=39$ n (%)	ADA-0.8mpk $N=38$ n (%)	ALL $N=114$ n (%)
Any TEAE	28 (75.7)	30 (76.9)	26 (68.4)	84 (73.7)
Infection	20 (54.1)	22 (56.4)	18 (47.4)	60 (52.6)
Serious	0	3 (7.7)	0	3 (2.6)

P055

Efficacy, safety of adalimumab versus methotrexate in pediatric patients with severe chronic plaque psoriasis: Results from the treatment withdrawal and double-blind retreatment periods of a phase 3 study

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Introduction: This study (NCT01251614) evaluated safety and efficacy of adalimumab (ADA) v methotrexate (MTX) treatment (Tx) in pediatric patients (pts) with chronic plaque psoriasis.

Objective: Report results from the Tx-withdrawal and double-blind (DB) retreatment (rTx) periods.

Methods: This multi-site international study included 4 Pds. PdA: 16-week DB Tx; 1:1:1 randomization to initial 0.8 mpk ADA up to 40 mg, then every-other-week (eow) from Wk1; initial 0.4mpk ADA up to 20 mg, then eow from Wk1; or 0.1–0.4mpk MTX weekly up to 25 mg/wk. Responders (≥PASI75 and Physician's Global Assessment [PGA] clear/minimal [0/1]) at end of PdA proceeded to PdB (non-responders proceeded to 52-week follow-up PdD). PdB: Tx withdrawal for PdA responders until loss of disease control (≥2 grade worsening of PGA v Wk16 PdA) up to 36 wks. PdC: pts with loss of disease-control in PdB had 16 weeks of rTx (blinded); ADA-0.8mpk for pts receiving ADA-0.8mpk or MTX in PdA; ADA-0.4mpk for pts receiving ADA-0.4mpk in PdA. Safety was evaluated for pts who received at least 1 dose of study drug (Table). Missing efficacy data in PdC (PGA 0/1) were imputed as non-responders.

Results: Of 114 enrolled pts (MTX $n=37$, ADA-0.4mpk $n=39$, ADA-0.8mpk $n=38$), 57% were female; 90% were white. Mean age was 13.0 yrs (SD 3.76, range 5–18). 54/114 (47.4%) were PdA responders and entered PdB (35.1%, 13/37 MTX, 46.1%, 18/39 ADA-0.4mpk, 60.5%, 23/38 ADA-0.8mpk). 70.4% (38/54) lost disease control in PdB and entered PdC; 75.0% (27/36), MTX and ADA-0.8mpk were rTx with ADA-0.8mpk; 61.1% (11/18) rTx with ADA-0.4mpk. In PdC, no pts had PGA 0/1 at Wk 0. After 16 wks, 55.6% (15/27) rTx with ADA-0.8mpk and 27.3% (3/11) rTx with ADA-0.4mpk had re-achieved PGA 0/1.

Conclusion: In PdC, a high percentage of pts regained PGA 0/1 response following rTx with ADA. RTx with ADA-0.8mpk had a similar safety profile to rTx with ADA-0.4mpk; no new safety risks were identified.

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[P055] Table 1. Treatment emergent adverse events (TEAEs) PdC

	rTx ADA-0.4mpk $N=11$ n (%)	rTx ADA-0.8mpk $N=27$ n (%)	All $N=38$ n (%)
Any TEAE	5 (45.5)	20 (74.1)	25 (65.8)
Infection	2 (18.2)	12 (44.4)	14 (36.8)
Serious	0	0	0

P056

Pregnancy outcomes in women with moderate to severe psoriasis: The PSOLAR experience

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Objective: We report pregnancy outcomes observed in PSOLAR, an international, longitudinal, observational study evaluating safety outcomes in psoriasis (PsO) pts eligible to receive treatment for PsO with biologics and/or conventional systemic agents.

Methods: Pregnancies and outcomes are reported by investigators and evaluated on a real-time basis by a medical monitor.Clarifying information may be requested, however routine verification of the outcome by an obstetrician is not required.

Results: As of Aug 23, 2014, PSOLAR is fully enrolled with 12,093 pts. There have been 172 pregnancies, of which 129 (75%) resulted in live birth, 31 (18%) ended in spontaneous abortion, 11 (6.4%) were electively terminated, and 1 (0.6%) did not have an outcome provided. The spontaneous abortion rate is comparable with the expected range of 15–20% in the general U.S. population. Among the 129 live born infants, 115 (89.1%) were full-term and 14 (10.9%) were born premature (<37 wks gestation). No congenital anomalies were reported. One stillbirth (0.8%) was reported in a 33 year-old pt with a history of previous spontaneous abortion and exposure to multiple="multiple" anti-TNF biologics on registry. Nine infants had a neonatal problem, including 1 ABO mismatch, respiratory issues (3 total: 2 related to prematurity, 1 related to aspiration pneumonia), 2 hospitalizations due to early delivery related to pre-eclampsia, 1 hyperemesis, 1 had opioid withdrawal, and 1 needed additional monitoring for hypoglycemia. 139 pregnancies occurred in women who with biologic exposure at some time prior to or during pregnancy; 33 occurred in women who were never exposed to a biologic.

Conclusions: In women enrolled in PSOLAR with moderate to severe PsO, there have been 172 pregnancies among 5,457 women (3.2%) not adjusted for age or child bearing status. The live birth rate was 75% and the spontaneous abortion rate was 18%, comparable with expected reported rates. No birth defects have been reported thus far. As data continue to accumulate, future work will focus on outcomes as they relate to specific PsO treatments, duration and timing.

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P057

Maintenance of efficacy results from UNCOVER-1: A phase 3 trial of ixekizumab for moderate-to-severe plaque psoriasis

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Introduction: IL-17A plays a key role in the pathogenesis of psoriasis.

Objective: The objective of this study was to evaluate the safety and optimal dosing interval for ixekizumab, an anti-IL-17A monoclonal antibody, in the maintenance of response during an additional 48 weeks of blinded treatment among patients who achieved an sPGA 0/1 following 12 weeks of induction therapy.

Methods: In this trial, 1,296 patients were randomized to receive subcutaneous placebo ($N=431$), or a single injection of 80 mg ixekizumab every 2 (IXE Q2W; $N=433$) or 4 weeks (IXE Q4W; $N=432$ following a 160 mg starting dose at Week 0. At Week 12, ixekizumab-treated patients who achieved sPGA 0/1 were re-randomized to receive placebo ($n=226$), 80 mg ixekizumab every 4 (IXE Q4W; $n=229$) or 12 weeks (IXE Q12W; $n=227$). Patients in any treatment arm, who did not achieve sPGA 0/1 at Week 12, received IXE Q4W through Week 60. Comparisons were done using logistic regression analysis. For response analyses, missing data was imputed using non-responder imputation method.

Results: At Week 60, sPGA 0/1 was maintained in 72.9%, 37.4% and 7.5% of patients in the IXE Q4W, Q12W, and placebo groups, respectively ($P<0.001$ for each comparison versus placebo). Complete resolution of psoriasis (PASI 100) was achieved at Week 60 by 52.0%, 20.3%, and 2.7% of patients in the IXE Q4W, Q12W, and placebo groups, respectively ($P<0.001$ for each comparison versus placebo). Exposure-adjusted, serious adverse event (SAE) rates (per 100 person-years) in the re-randomized population were 8.0, 5.8, and 6.8 in the IXE Q4W, Q12W, and placebo groups, respectively. By comparison, SAE rates at Week 12 were 6.0, 12.2, and 5.2, for IXE Q2W, Q4W, and placebo groups, respectively.

Conclusions: IXE Q4W was effective at maintaining sPGA 0/1 over 60 weeks and over 50% of patients achieved complete resolution of their psoriasis by Week 60. These results provide further evidence for the long-term effectiveness of ixekizumab. The exposure-adjusted SAE rates in patients re-randomized to the Q4W dose were comparable in the maintenance period through Week 60 relative to the 12 week induction period.

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P058

A phase 3 trial comparing ixekizumab with placebo and etanercept for moderate-to-severe plaque psoriasis: Results from the 12 week induction period of UNCOVER-2

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Introduction: IL-17A plays a key role in the immunopathogenesis of psoriasis.

Objectives: To evaluate the efficacy and safety of an anti-IL-17A monoclonal antibody, ixekizumab, for the treatment of psoriasis.

Methods: In this double-blind trial, 1,224 patients were randomized to receive subcutaneous placebo ($N=168$), etanercept (50 mg twice weekly; $N=358$), or a single injection of 80 mg ixekizumab every 2 (IXE Q2W; $N=351$) or 4 weeks (IXE Q4W; $N=347$) following a 160 mg starting dose. The co-primary efficacy endpoints were proportions of patients who achieved 1) ansPGA 0/1, and 2) PASI 75 by Week 12. Treatment groups were compared using the Cochran-Mantel-Haenszel test. For response analyses, missing data were imputed using non-responder imputation.

Results: At Week 12, PASI 75 response rates were 89.7% in IXE Q2W, 77.5% in IXE Q4W, 2.4% in placebo, and 41.3% in etanercept groups , and sPGA 0/1 was achieved by 83.2% in the IXE Q2W, 72.9% in IXE Q4W 2.4% in placebo, and 36.0% in etanercept groups ($P<0.001$ each ixekizumab versus placebo or etanercept). Differences were seen as early as Week 1 for IXE Q2W and IXE Q4W compared to the etanercept group ($P<0.05$). Complete resolution (PASI 100) was achieved 40.5% in IXE Q2W, 30.8% in IXE Q4W , 0.6% in placebo, and 5.3% in etanercept groups ($P<0.001$ each ixekizumab versus placebo or etanercept). Treatment-emergent adverse events reported in ⩾5% of ixekizumab-treated patients and at higher percentages than in placebo-treated patients included injection-site reaction and headache, most of which were mild to moderate in severity. The percentages of these events in ixekizumab-treated patients were similar to those in etanercept-treated patients. Serious adverse events were reported in 1.4% of IXE Q2W, 1.7% of IXE Q4W, 1.2% of placebo, and 1.7% of etanercept patients.

Conclusions: Both ixekizumab dosing regimens were highly effective and superior to placebo and etanercept with onset of efficacy as early as Week 1 and a safety profile comparable to etanercept in this induction period. Over 75% of ixekizumab-treated patients achieved PASI 75, and over 30% achieved complete resolution of psoriasis.

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P059

A phase 3 trial comparing ixekizumab with placebo and etanercept for moderate-to-severe plaque psoriasis: Results from the 12 week induction period of UNCOVER 3

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Introduction: IL-17A plays an important role in the immunopathogenesis of psoriasis.

Objectives: To assess the efficacy and safety of an anti-IL-17A monoclonal antibody, ixekizumab, for the treatment of psoriasis.

Methods: In this double-blind trial, 1346 patients were randomized to receive subcutaneous placebo ($N=193$), etanercept (50 mg twice weekly; $N=382$), or a single injection of 80 mg ixekizumab every 2 (IXE Q2W; $N=385$) or 4 weeks (IXE Q4W; $N=386$) following a 160 mg starting dose. The co-primary efficacy endpoints were proportions of patients who achieved 1) an sPGA 0/1, and 2) PASI 75 at Week 12. Treatment groups were compared using the Cochran-Mantel-Haenszel test. For response analyses, missing data were imputed using non-responder imputation (NRI).

Results: At Week 12, PASI 75 response rates were 87.3% in IXE Q2W, 84.2% in IXE Q4W, 7.3% in the placebo, and 53.4% in etanercept groups, and sPGA 0/1 was achieved by 80.5% in IXE Q2W, 75.4% in IXE Q4W, 6.7% in placebo, and 41.6% in etanercept groups ($P<0.001$ each ixekizumab versus placebo or etanercept). Differences were seen as early as Week 1 for IXE Q2W and IXE Q4W compared to the etanercept group ($P<0.05$). Complete resolution (PASI 100) was achieved by 37.7% in IXE Q2W, 35.0% in IXE Q4W, 0 in placebo, and 7.3% in etanercept groups ($P<0.001$ each ixekizumab versus placebo or etanercept). Treatment-emergent adverse events reported in ⩾5% of all ixekizumab patients and at higher percentages than in placebo patients included injection-site reaction and nasopharyngitis. Most of these events were mild to moderate in severity. The percentages of these events in ixekizumab patients were similar to those in etanercept patients. Serious adverse events were reported in 2.3% of IXE Q2W, 1.6% of IXE Q4W, 2.6% of placebo, and 1.3% of etanercept patients.

Conclusions: Both ixekizumab dosing regimens were highly effective and superior to placebo and etanercept with onset of efficacy as early as Week 1 and a safety profile comparable to etanercept in this induction period. Over 80% of ixekizumab-treated patients achieved PASI 75, and over 35% achieved complete resolution of psoriasis.

Disclosure of Interest: C. E. Griffiths Grant/Research support from: AbbVie, Janssen, Celgene, Eli Lilly, MSD, Bristol Meyers Squibb, Novartis, Sandoz, LEO, Trident, Regeneron, Consultant of: Abbvie, Actelion, Janssen, Amgen, Eli Lilly, Celgene, Pfizer, Sandoz,UCB Pharma, GSK-Stiefel, LEO; K. Reich Consultant of: AbbVie, Amgen, Biogen-Idec, Celgene, Centocor, Covagen, Eli Lilly, Forward Pharma, GlaxoSmithKline, Janssen-Cilag, LEO Pharma, Medac, MSD, Novartis, Ocean Pharma, Pfizer, Regeneron, Takeda, UCB, Vertex, Xenoport, Speakers bureau of: AbbVie, Amgen, Biogen-Idec, Celgene, Centocor, Covagen, Eli Lilly, Forward Pharma, GlaxoSmithKline, Janssen-Cilag, LEO Pharma, Medac, MSD, Novartis, Ocean Pharma, Pfizer, Regeneron, Takeda, UCB, Vertex, Xenoport; M. Lebwohl Grant/Research support from: AbGenomics, Amgen, Anacor, Canfite Biopharma, Celgene, Clinuvel, Coronado Biosciences, Ferndale, Consultant of: Dermipsor; P. Van de Kerkhof Consultant of: Celgene, Centocor, Allmirall, Amgen, Psizer, Phillips, Abbott, Eli Lilly, Galderma, Novartis, Janssen, Cilag,Leo Pharma , Mitsibishi, Sandoz; C. Paul Grant/Research support from: Pienne Fabre, Consultant of: Pfizer, Abbvie, Amgen, Celgene, Janssen, Eli Lilly, Leo, Novartis, GSK; A. Menter Grant/Research support from: AbbVie, Allergan, Amgen, APoPharma, Beohringer Ingelheim, Cengene, Convoy Therapeutics, Eli Lilly, Genentech, Janssen Biotech, Leo Pharma, Merck, Novartis, Pfizer, Symbio, Syntrix, Wyeth, XenoPort, Consultant of: AbbVie, Allergan, Amgen, Convoy Therapeutics, Eli Lilly and Company, Janssen Biotech, Novartis, Pfizer, Syntrix, Wyeth, Xenoport, Speakers bureau of: AbbVie, Amgen, Janssen Biotech, Leo Pharma, Wyeth; H. Carlier (presenter only) Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company; G. Cameron Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company; J. Erickson Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company; L. Zhang Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company; R. Secrest Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company; S. Ball Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company; D. Braun: None to declare; O. Osuntokun Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company; M. Heffernan Shareholder of: Eli Lilly and Company, Consultant of: Eli Lilly and Company; B. Nickoloff Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company; K. Papp Grant/Research support from: Abbott, Amgen, Anacor, Astellas, Celgene, Celtic, Dow Pharma, Eli Lilly, Galderma, Consultant of: Abbott, 3M, Akesis, Allergan, Alza, Amgen, Astellas, Baxter, Boehringer Ingelheim, Celgene, Centocor, Cipher, Eli Lilly and Comany, Forward Pharma, Funxional therapeutics, Speakers bureau of: Abbott, Akesis, Amgen, Astellas.

P060

Complete resolution of psoriasis is associated with greater improvements in itch and health-related quality of life: an analysis from UNCOVER-2, a phase 3 clinical trial of ixekizumab

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Introduction: Psoriasis has serious impacts on health related quality of life (HRQoL), and itch is an important symptom for many patients. Currently, PASI 75 is considered a good treatment goal for psoriasis patients; however, individuals not achieving complete resolution of psoriatic lesions (ie PASI 100) may have continued impairment in HRQoL.

Objective: To evaluate differences in patient reported outcomes (PROs) among individuals who achieve PASI 100 compared to those with lower treatment responses in patients with psoriasis participating in a trial of ixekizumab, an anti-IL-17A monoclonal antibody.

Methods: In this trial, 1224 patients were randomized to receive subcutaneous placebo, etanercept (50 mg twice weekly), or a single injection of 80 mg ixekizumab every 2 or 4 weeks following a 160 mg starting dose. Treatment groups were combined for the analyses. PROs included the Itch Numeric Rating Scale (Itch NRS), which ranges from 0 to 10 (no itch to severe itch), and the DLQI(scores of 0–1 are interpreted as disease having no effect at all on a patient's life). Improvements in PROs at week 12 were compared pairwise between groups of patients achieving <50% improvement in PASI (PASI <50 [$N=354$]), 50%> < 75% improvement in PASI (PASI 50-<75 [$N=134$]), 75%> < 90% improvement in PASI (PASI 75-<90 [$N=213$]), 90%> <100% improvement in PASI (PASI 90-<100 [$N=254$]), and 100% improvement in PASI (PASI 100 [$N=269$]).

Results: Greater improvements in DLQI and Itch NRS were associated with greater improvements in psoriasis with maximum improvements in the PASI 100 group ($P<0.01$ for all pairwise comparisons between subgroups). In the PASI 100 group, there were significantly greater reductions in Itch NRS (-5.9 versus -4.6, respectively; $P<0.01$) and more patients with a DLQI score of 0 or 1 (78% versus 53%, respectively; $P<0.01$) compared to the PASI 75-<90 group.

Conclusions: Maximum reductions in itching and the highest percentage of patients reporting no impact of psoriasis on HRQoL were observed among those who achieved complete resolution of psoriasis compared to those achieving lower levels of response suggesting that clear skin is a desirable treatment goal for patients.

Disclosure of Interest: C. Griffiths Grant/Research support from: AbbVie, Janssen, Celgene, Eli Lilly, MSD, Bristol Meyers Squibb, Novartis, Sandoz, LEO, Trident, Regeneron, Pfizer, Consultant of: Abbvie, Actelion, Janssen, Amgen, Eli Lilly, Celgene, Pfizer, Sandoz,UCB Pharma, GSK-Stiefel, LEO; A. Blauvelt Consultant of: AbbVie, Amgen, Boehringer Ingelheim, Celgene, Janssen; M. Lebwohl Grant/Research support from: AbGenomics, Amgen, Anacor, Canfite Biopharma, Celgene, Clinuvel, Coronado Biosciences, Ferndale, Consultant of: Dermipsor; A. Bleakman (presenter only) Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company; E. Nikai Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company; O. Goldblum Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company; K. Reich Grant/Research support from: AbbVie, Amgen, Biogen-Idec, Celgene, Centocor, Covagen, Eli Lilly, Forward Pharma, GlaxoSmithKline, Janssen-Cilag, LEO Pharma, Medac, MSD, Novartis, Ocean Pharma, Pfizer, Regeneron, Takeda, UCB, Vertex, Xenoport; Consultant of: AbbVie, Amgen, Biogen-Idec, Celgene, Centocor, Covagen, Eli Lilly, Forward Pharma, GlaxoSmithKline, Janssen-Cilag, LEO Pharma, Medac, MSD, Novartis, Ocean Pharma, Pfizer, Regeneron, Takeda, UCB, Vertex, Xenoport.

P061

Comparison attainment of minimal disease activity and state of ultrasound remission after one year of treatment-to-target strategy in early psoriatic arthritis

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Background: Minimal disease activity (MDA) predicts less radiographic damage in peripheral joints in psoriatic arthritis (PsA). The relationship between MDA and ultrasound (US) findings in early PsA (EPsA) has not been studied yet.

Objective: to evaluate the association between MDA and US remission during one year of T2T strategy in EpsA.

Methods: 25 (M/F—9/16) DMARD-naïve patients (pts) with active EPsA, according to the CASPAR criteria, mean age 38.6 ± 10.3 years, PsA duration 12 [5; 24] months (mo), psoriasis duration 36 [12; 84] mo., DAS 3.9 [3.1; 4.7], CRP 15 [9.7; 25.1]mg/l were included to REMARCA [**R**ussian inv**E**stigation of **M**ethotrex**A**te and biologics in ea**R**ly a**C**tive inflammatory **A**rthritis] study. The dose of Methotrexate (MTX) subcutaneous was 20–25 mg/wk. If pts do not achieve MDA after 3 mo. of MTX-mono therapy than Adalimumab 40 mg every two wks was added. At baseline and at 12 mo. of therapy all pts underwent clinical examination, CRP and US assessment of the wrist, 2–3 metacarpophalangeal, 2–3 proximal interphalangeal, 2–5 metatarsus-phalangeal joints by LOGIQ-9. US active synovial inflammation/US remission (US-ReM) were defined as the presence or absence of vascularization—Power Doppler (PD) ⩾ 1/PD = 0 accordingly. At 12 mo. of therapy the proportion of pts who achieved MDA and US-ReM were calculated. M ± SD, Me [Q75; Q50], (%), Fisher's exact, Spearmen correlations coefficient (R) was calculated. All $P<0.05$ were considered to indicate statistical significance.

Results: At baseline PD⩾1 was detected in 12 (48%) out of 25 pts. Significant positive correlations were found between PD⩾1 and CRP (R = 0.45, $P=0.023$), DAS (R = 0.54, $P=0.006$). By 12 mo. of therapy DAS/CRP significantly decreased to 1.5 [1.0; 2.2]/2.3[1.5; 3.3] respectively (Fisher's exact $P<0.001$). Significant negative correlations were found between PD⩾1 and MDA (R = −0.48, $P=0.016$). By 12 mo. of therapy MDA was seen in 17 (68%) pts. Among those who achieved MDA, US-ReM was seen in 16 (94.1%) pts.

Conclusion: Vascularization by US is strongly associated with EPsA activity and MDA. It can be useful for monitoring of the treatment and the attainment of MDA during one year of T2T strategy.

Disclosure of Interest: None to declare.

P062

Anti CD 6 molecule tolizumab shows promising result in von Zumbusch GPP

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Introduction: Generalized pustular psoriasis (von Zumbusch) is characterized by fever, chills, polyarthralgia, and malaise for several days followed by development of sterile pustules 2–3 mm in diameter, disseminated over trunk and extremities. It can be a life threatening condition and requires a potent and rapid onset treatment regimen.[1,2]

Objectives: Aim of this study was to find quick response, long term remission and to establish safety & efficacy of anti CD6 molecule Itolizumab. Itolizumab is a novel anti CD-6 humanized monoclonal antibody which works upstream by inhibiting the co-stimulation of T cells, lowering release of signature cytokines of Th1 & Th 17 cells.

Methods: A female patient was included in the study, was on oral corticosteroids for more than 8 months which was stopped abruptly. She developed erythroderma, polyarthralgia, fever and malaise followed by pustules, was admitted and investigated, TLC was raised. Informed consent was taken for itolizumab infusion. A dose of 1.6 mg/kg body weight was given by intra venous route for 10 infusions, 6 infusions at 15 days intervals and rest 4 at monthly intervals to maintain the desired serum level of C min >10ugm/ml. The patient was intolerant to conventional immunosuppressant/immunomodulator.

Results: All constitutional symptoms were reduced within 24 hours of 1st infusion. A statically significant improvement in PASI at baseline to PASI at the 10th infusion was achieved and similar results were obtained in DLQI &, PGA. PASI—53 DLQI-27 before Itolizumab. After 28 weeks PASI—0.8 DLQI-3.

Conclusion : Itolizumab a novel anti CD-6 is safe and efficacious in the management of von Zumbusch psoriasis.This is probably the 1st case report showing rapid response of biologics in von Zumbusch GPP.

Disclosure of Interest: None to declare.

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P063

Successful treatment with ustekinumab in 3 patients with palmoplantar psoriasis

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Introduction: Palmoplantar psoriasis (PPP) is rare and incapacitating. Conventional treatments are partially effective, even anti-TNF.

Objective: Present successful response to Ustekimunab treatment in patients with PPP.

Method: The files of three patients with PPP were reviewed, to describe the evolution and response to Ustekinumab treatment.

Results: CASE 1: 58 year-old female, had moderated PPP. Conventional treatments achieved partial remission. Life quality index (DLQI) was 15. She developed severe depression due to public rejection, so she retired. She got worse with Anti-TNF (Adalimumab) treatment. Ustekinumab 45 mg every 3 moths was started, 70% improvement two weeks after the second dose. CASE 2: 54 year-old female, with diabetes and hypertension, had moderate PPP. DLQI was 20. She had partial remission with methotrexate. She got worse with Anti-TNF (Etanercept). Ustekinumab 45 mg every 3 months was started. By the third dose all the lesions was gone. CASE 3: 35 year-old female, had severe scalp and PPP with alopecia where the patches were more severe. DLQI was 14. No response to conventional treatments and all anti-TNF inhibitors. Isotretinoin 1 mg/kg/day was started with 50% improvement. She had urinary tract infection, with relapse to initial lesions. Ustekinumab 45 mg every 3 months treatment was started. She had total improvement in scalp and palms, 80% in soles.

Conclusions: PPP treatment is a therapeutic challenge. No agreement in the treatment of this PPP, neither a standardized strategy. These cases are excluded from the clinical and pharmacological studies. PPP treatment with Ustekinumab was successful in these patients. We think that Ustekinumab can be used as a first line therapy in PPP.

Disclosure of Interest: None to declare.

P064

Retrospective analysis of the use of the European Treatment Goal Consensus criteria in a psoriasis-specialized center prior to their introduction

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Psoriasis is a chronic, inflammatory disease that requires long-term control particularly in patients with moderate-to-severe involvement. For these patients systemic therapy is indicated according to international guidelines.

In 2011 a European Consensus on treatment goals for moderate-to-severe psoriasis was published and is now widely used or already implemented into national guidelines. The aim of this consensus is to secure an effective therapy during induction and maintenance phase of systemic therapy. In the consensus not achieving a PASI50 was defined as treatment failure and achieving a PASI75 as treatment success.

In the present study we aimed to answer the question, if treatment at a center specialized in psoriasis already followed these criteria before they were implemented. For this purpose a retrospective chart review was done and 1,014 psoriasis patients analysed that were registered in the database of the Psoriasis-Center at the Dept. of Dermatology, University Medical Center Schleswig-Holstein, Campus Kiel, Germany. Of these 1,014 patients 199 could be selected for further analysis between 2006 and 2012.

The best therapeutic effect was seen with ustekinumab followed by adalimumab and infliximab. Among the conventional drugs fumarates were superior to methotrexate that was the favored drug for combination therapy.

In the patient cohort 86 changes of treatment were noted, mostly in the induction phase of treatment. In most cases inadequate response was the reason to change. However, there was no stringent switch to another therapy in case of inadequate response (defined as not achieving PASI50) during this period of time with no treatment goals established.

The data substantiate the need for treatment goals in routine psoriasis management to secure effective treatment particularly during maintenance therapy.

Disclosure of Interest: None to declare.

P065

Itolizumab- A new biologic for management of psoriasis and psoriatic arthritis

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Introduction: The use of biologics is expanding in the treatment of extensive forms of unstable psoriasis and chronic plaque type of psoriasis. Most of the biologics act by inhibiting TNF alpha receptors by competitively binding to it. A new molecule Itolizumab developed and used in India, is a humanized recombinant anti- CD6 monoclonal antibody of IgG1 isotype that binds to domain 1 of anti-CD6 thereby it immunomodulates human lymphocytes without interfering with the binding of CD6 to ALCAM.

Objectives: Itolizumab was used with the aim of rapid reduction and control of complicated and extensive psoriasis.

Methods: Observational study. Five patients who had undergone prolonged cycles of methotrexate and cyclosporine therapy with poor response were treated with Itolizumab. Out of five patients four patients had chronic plaque psoriasis and one patient had psoriatic erythroderma along with psoriatic arthropathy. The regimen was bimonthly cycles administered intravenously in 0.9% normal saline at the dose of 1.6 mg/kg for three months followed by maintenance with monthly cycles for three months.

Results: Patients showed significant improvement after completion of the infusion. All five patients had achieved >PASI 95. Recalcitrant plaques of psoriasis resolved completely leaving behind areas of hyperpigmentation. Psoriatic arthropathy also improved significantly. The infusion was well tolerated by all the patients with no infusion reactions or infections during the treatment period.

Conclusion: Itolizumab is a novel therapy for the management of extensive psoriasis offering hope for those affected. It is also much more affordable than currently available other monoclonal antibodies with comparable efficacy.

Disclosure of Interest: None to declare.

P066

Ixekizumab impact on itch severity compared to etanercept and placebo: Results from UNCOVER-2, a phase 3 trial in patients with moderate-to-severe plaque psoriasis

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Introduction: Itch is a significant and persistent symptom affecting many psoriasis patients and is associated with markedly decreased quality of life.

Objectives: To evaluate the effect of ixekizumab treatment on itching severity in patients with psoriasis compared to etanercept and placebo.

Methods: In this trial, 1,224 patients with psoriasis were randomized to receive subcutaneous placebo ($N=168$), etanercept (50 mg twice weekly; $N=358$), or a single 80 mg injection of ixekizumab once every 2 (IXE Q2W; $N=351$) or 4 weeks (IXE Q4W; $N=347$) following a 160 mg initial dose at week 0. Itching severity was assessed using the Itch Numeric Rating Scale (Itch NRS), a patient-reported, single-item, 11-point scale where 0 represents ''no itch'' and 10 represents ''worst itch imaginable'' in the past 24 hours. Improvement in itch and the percentage of patients with a prespecified response ($\geq$4-point score reduction from baseline) or with Itch NRS = 0 at week 12 were compared between treatment groups using mixed effects model for continuous variables and the Fisher exact test or a logistic model for categorical variables after imputing the missing values using non-responder imputation (NRI).

Results: Average baseline Itch NRS score across groups was 6.6. Significant improvements in itching severity were observed compared to placebo and etanercept ($P<0.001$) as early as week 1. By week 12, changes in Itch NRS scores in the IXE Q2W (-5.2) and IXE Q4W (-4.9) treatment groups remained significantly larger compared to placebo (-0.4; $P<0.001$) and etanercept (-3.6; $P<0.001$). Among patients with baseline Itch NRS of $\geq$4 points, the proportions of patients who had a $\geq$4-point reduction in Itch NRS scores were significantly greater in the IXE Q2W (84.8%) and IXE Q4W (76.8%) groups versus placebo (14.1%; $P<0.001$) and etanercept (57.2%; $P<0.001$). More patients had Itch NRS = 0 at week 12 in the IXE Q2W (40.7%) and IXE Q4W (40.6%) groups compared to placebo (2.4%; $P<0.001$) and etanercept (17.3%; $P<0.001$).

Conclusions: Ixekizumab-treated patients reported significantly greater and more rapid improvements in itching severity as measured by the Itch NRS compared to placebo and etanercept over 12 weeks.

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P067

Experience with ustekinumab for the treatment of moderate-to-severe cutaneous psoriasis in our clinical practice setting

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Introduction: Ustekinumab is a human monoclonal antibody that reduces the expression of interleukin-12 and interleukin-23, key inflammatory cytokines involved in the pathogenic mechanisms of psoriasis. Current data from clinical trials indicate ustekinumab is safe and efficacious.

Objectives: The aim of the study is to evaluate the performance of ustekinumab in a routine care setting, evaluating patterns of use, treatment response, drug survival and safety, as well as possible factors involved in ustekinumab clinical response.

Methods: We have evaluated retrospectively all the moderate-to-severe cutaneous psoriasis treated for at least 6 months with ustekinumab since 2009, in our clinical practice settings. Data regarding psoriasis history, clinical characteristics, HLA-Cw6 status, previous and concomitant treatments, ustekinumab dosage, clinical response and adverse events was recorded, among others.

Results: 36 patients were included in the study (21 men and 15 women) with an average age of 49 years old, and an average history of psoriasis around 22 years. The most frequent clinical presentation was chronic big plaque psoriasis, and in 16% of cases, concomitant psoriatic arthritis was present. All the patients had previously received at least one classic systemic treatment, and 38% were naive to biologicals. 72% of patients achieved PASI75 at week 16, increasing to 77% at week 24. In 30% of patients, ustekinumab was combined with another systemic treatment, mainly metothrexate, in order to maintain or regain efficacy, followed by systemic transition or psoriatic arthritis control. 30% of the patients discontinued ustekinumab treatment, due to primary or secondary failure, followed by loss of follow-up, adverse events, efficacy and pregnancy desire. A serious adverse event was described in two patients, one of which required ustekinumab discontinuation.

Conclusions: In our patients, ustekinumab is an effective treatment for moderate-to-severe psoriasis, with elevated survival rates, and results comparable to clinical trials.

Disclosure of Interest: None to declare.

P068

Sustained remission achieved with itolizumab in patients with chronic plaque psoriasis- Real world experience

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Introduction: Itolizumab is a humanized recombinant anti-CD6 monoclonal antibody which is currently approved in India for treatment of active moderate to severe chronic psoriasis in patients eligible for systemic therapy. Itolizumab exerts an immunomodulatory action on T cells which in turn leads to prolonged control of psoriasis symptoms and lesser incidence of infections. Phase 3 results of itolizumab showed it to be a promising biologic. Here we present the real world experience of Itolizumab in patients with chronic plaque psoriasis.

Objectives: To assess the remission period, efficacy and safety of itolizumab in real world scenario.

Methods: Observational study in 10 patients with chronic plaque psoriasis. Itolizumab was administered as per manufacturer recommendations ie once every fortnight for 3 months followed by once every month for next 3 months. PASI scores were assessed at every infusion visit. Remission period was considered to be duration for which the patients maintained response of PASI 50 after completion of 10 infusions. Adverse events during the treatment period were recorded.

Results: All patients achieved PASI 50 response. PASI 75 was achieved by 6 patients out of 10. Average duration of remission achieved was 6 months following 10 infusions. Mild infusion reactions were observed .No serious adverse events were observed in the patients studied.

Conclusion: The results obtained are comparable to results obtained in Phase 3 Itolizumab study. Even though PASI 50 was maintained, maintenance dose of itolizumab on monthly or once in three months would be required to maintain higher than PASI 50 response.

Disclosure of Interest: None to declare.

P069

PsoBest: Drug safety in systemic treatments for psoriasis and psoriatic arthritis

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Introduction: The German National Psoriasis registry PsoBest aims to investigate the long-term outcomes and safety of systemic treatments for moderate to severe psoriasis since 2008.

Objectives: Safety analysis of antipsoriatic drugs with special focus on serious adverse events (SAE) and psoriatic arthritis (PsA).

Methods: Data is used from PsoBest, a nationwide non-interventional patient treatment registry. Standardized event rates per 100 patient years (PY) were calculated and classified by treatment.

Results: Until June 2014 3,322 patients were registered (40.5% female, 47 years, 19% PsA). In total 2,704 PY with biologic treatment have been observed, 3,787 PY on conventional systemic treatment. There were no significant differences in rates regarding sex. Patients receiving biologic treatment show a higher risk for general disorders and surgical procedures (1.61 versus 0.03 pat/100PY and 2.4 versus 1.11 pat/100PY, $P<=0.05$), since risk for endocrine disorders is decreased (0.04 versus 1.5 pat/100PY, $P<=0.05$). Rates for SAE are not different for patients in conventional systemic treatment in respect of presence of PsA. Patients with PsA show higher rates for surgical procedures and gastrointestinal disorders when they receive a biologic treatment (3.29 versus 1.53 pat/100PY and 0.75 versus 0.0 pat/100PY, $P<=0.05$). Other rates, eg immune system or vascular disorders are similar for the groups. Neoplasms were observed with 0.86 pat/100PY in biologic and 0.7 pat/100PY in conventional systemic treatment ($P>0.05$), all cause death almost identically with 0.48 versus 0.51 pat/100PY.

Conclusions: In total, with respect to safety signals, there have not been observed any indications for elevated risks of using systemic or biologic drugs in patients with PsA. Low-level differences found indicate a satisfying safety of the systemic and biological drugs used in Germany for psoriasis, which are in line with results of recent publications of psoriasis registries from different countries.[1]

Disclosure of Interest: None to declare.

References:

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P070

PASI scores by body region with adalimumab in patients with suboptimal response to prior therapy

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Introduction: Psoriasis (Ps) severity and treatment response vary by body region. Overall Psoriasis Area and Severity Index (PASI) represents a composite that does not indicate disease activity in individual body regions.

Objectives: Evaluate the efficacy of adalimumab (ADA) by body region in patients (pts) with a suboptimal response to prior Ps therapy.

Methods: In the 16-wk, open-label, phase 3b PROGRESS trial,[1] 152 pts with moderate to severe plaque Ps and prior suboptimal response to methotrexate (M), etanercept (E), or UVB phototherapy (P) received an initial 80-mg dose of ADA and then 40 mg every other wk from wk 1. PASI (range, 0–72) was calculated overall and by body region; missing data were imputed (last observation carried forward). Safety was assessed using adverse events (AEs).

Results: Screening characteristics were similar among the 3 groups, except for a low rate of psoriatic arthritis in P (Table). Overall PASI mean improvements at wk 16 were 60.3%, 53.5%, and 63.1% for pts who switched from M, E, and P, respectively. Regional PASI mean improvements at wk 16 for pts who switched from M, E and P, respectively, were greatest for the trunk (85.0%, 65.9%, 69.2%) and head (71.1%, 65.1%, 79.9%), followed by the upper (64.1%, 51.5%, 69.8%) and lower (56.1%, 51.6%, 56.8%) extremities. The percentage of pts achieving PASI 0 or 1 (clear or almost clear) after switching from M, E, and P, respectively, was 31.7%, 12.2%, and 20.7% (overall score), 78.0%, 57.3%, and 65.5% (trunk), 75.6%, 72.0%, and 75.9% (head), 58.5%, 35.4%, and 37.9% (upper extremities), and 56.1%, 24.4%, and 31.0% (lower extremities). Most pts across arms (93.9%–97.6%) had no AEs or only mild to moderate AEs; AE incidence was 44.8%–61.0% among arms.

Conclusions: PASI improved in all body regions, particularly the head and trunk, in pts switched to ADA after failure of prior therapies.

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[P070] Table 1

	M $n=41$	E $n=82$	P $n=29$
Age, y, mean (SD)	47.4 (13.1)	48.3 (13.7)	45.7 (14.6)
Male, n (%)	28 (68.3)	47 (57.3)	16 (55.2)
Ps duration, y, mean (SD)	19.8 (13.5)	17.2 (12.0)	23.0 (14.1)
Psoriatic arthritis, n (%)	17 (41.5)	47 (57.3)	7 (24.1)

EPIDEMIOLOGY

P072

Serum ferritin levels as an indicator of anemia in moderate to severe psoriasis patients compared to the general public

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Introduction: Psoriasis (PsO) is a chronic auto-immune disorder that affects apx. 2% of the population. It is considered to exhibit a systemic chronic inflammatory state and may contribute to multiple co-morbidities including psoriatic arthritis, cardiovascular disease and cutaneous T-cell lymphoma. Iron deficiency, affecting apx. 2–5% of men and post-menopausal women in the developed world is believed to be associated with other inflammatory conditions such as Crohn's disease, however no literature could be found studying any possible relationships between PsO and iron deficiency. One of the most powerful tools for diagnosing iron deficiency is serum ferritin with an AUC of 0.95.

Objectives: To review Serum Ferritin Levels as an Indicator of Anemia in Moderate to Severe PsO Patients as Compared to the General Public.

Methods: A retrospective cohort study will be conducted using data abstracted from medical records of confirmed cases of moderate to severe plaque PsO as per a dermatologist. A chart audit will be conducted on approximately 200 cases which will then be matched to 600 controls. Most of these patients will be on a biologic (organically derived) therapy which may confound inflammation levels therefore data will be extracted pre- biologic therapy. Other potential confounding variables will be collected and used in a multivariate regression in order to test for a relationship between PsO and iron deficiency.

Results: Our preliminary study of 78 patients we have seen a significantly higher incidence of diagnosable iron deficiency in PsO patients (39%) as compared to the general population (2%). It is important to note that serum ferritin levels are an excellent indicator of iron deficiency in the absence of inflammation. Since individuals with PsO are more likely to show chronic inflammation, the analysis will have to account for this potential confounding.

Conclusion: Low serum ferritin is diagnostic of iron deficiency: <12–15 µg/l can result in a diagnosis of iron deficiency, <50 µg/l when there is an inflammatory disease such as PsO and >100 µg/l indicates that iron deficiency is unlikely (Fardy, 2014).

Disclosure of Interest: None to declare.

P071

Treatment of palmoplantar pustulosis and psoriasis with ustekinumab

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Introduction: Palmoplantar pustulosis (PPP) and palmoplantar psoriasis still remain difficult to treat. As palms and soles are affected patients can be severely disabled in their daily activities and do carry a significant burden of disease. Therefore efficient therapies are clearly warranted.

Objectives: To evaluate the efficacy of ustekinumab in the treatment of palmoplantar psoriasis and PPP.

Methods: Nine patients with PPP (eight females and one man, aged 26–57 years, mean age 45.4 years) and 4 males with palmoplantar psoriasis (aged 32–51 years, mean age 44.3 years) were treated with ustekinumab. Patients <100 kg received 45 mg, patients >100 kg 90 mg ustekinumab subcutaneouslyaccording to label. PPASI was evaluated at baseline, week 16 as well as week 28.

Results: At week 16 PPASI 50 was achieved by 5 patients (55.6%) with PPP, PPASI 75 and PPASI 90 was achieved by one patient each of PPP patients (11.1%) . No patient suffering from PPP displayed PPASI 100. Seventy-five percent of the patients (3 patients) with palmoplantar psoriasis showed a PPASI 75 at week 16 and one patient reached PPASI 100.

Results at week 28 were as follows: 33.3 % (3 patients) of PPP patients achieved PPASI 50, 55.6 % (five patients) a PPASI 75, and one PPASI 90, respectively. All four patients with palmoplantar psoriasis achieved PPASI 100 at week 28. Serious adverse events were noted in one patient (erysipelas).

Conclusions: Ustekinumab has been shown to be efficient in the treatment of PPP and palmoplantar psoriasis. However response to ustekinumab treatment in patients with PPP tends to take longer than in patients with palmoplantar psoriasis.

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P073

An examination of biologic treatment groups of psoriasis patients in a cohort of the Newfoundland and Labrador population

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Introduction: Research regarding biologics treatment for psoriasis (PsO) is quite limited given that biologics treatments were introduced only within the past ten years. In this study, the distribution of PsO patients by biologic treatment type, demographic factors and prognostic factors was examined. Health service utilization (hospital and physician visits) and comorbidities among PsO patients by biologic treatment type was also described.

Objectives: Cross-sectional study will assist in understanding the different biologics treatments, associated factors and comorbidities among a sample of PsO patients in the NL population.

Methods: This study involved linking medical records of confirmed cases of PsO patients obtained from a private dermatology clinic in St John's to administrative health databases to obtain patients' conditions.

Results: The majority of patients receiving biologics treatment had moderate/severe PsO. Signs and ill-defined conditions, skin/sub-cutaneous diseases, respiratory disease, nervous system/sense organs disease and musculoskeletal /connective tissue diseases were some of the most common comorbidities found across all biologic classes. Among biologics patients, 63.7% had at least one unique hospital separation, and 96.3% had at least one physician visit. The Charlson Comorbidity Index (CCI) which predicts one year mortality for patients with many comorbid conditions was significantly higher in female patients (2.37) as compared to male patients (1.93) $P<0.05$ on biologics. Of the biologics patients whose PsO Area and Severity Index (PASI) scores were available, 86.1% saw improvements after biologics treatment.

Conclusion: In this cohort of 284 patients female patients had significantly greater number of comorbidities (9.53 versus 8.20) $P<0.05$. Findings suggest the majority of patients receiving biologics had multiple associated comorbidities, and that females had significantly greater number of comorbidities (9.53 versus 8.20, $P< 0.05$). Also the Charlson Comorbidity Index which predicts one year mortality for patients with many comorbid conditions was significantly higher in females (2.37) as compared to male patients (1.93) $P<0.05$ on biologics.

Disclosure of Interest: W. Gulliver Grant/Research support from: *Funded by an Unrestricted Grant from Abbott Laboratories; D. D. MacDonald: None to declare.

P074

Analysis of psoriasis patients visiting Korean medical clinics

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Introduction: This paper examines clinical features of psoriasis patients who visit Korean Medical Clinic.

Objectives: Analyze patients' visits showing features and when psoriasis appears. Help doctors in clinical practice.

Methods: From 2007–2014, gave questionnaire survey to 1,738 patients (men: 826, women: 912) at specialized psoriasis clinics. Welch's T, Chi-square, and proportion tests used for statistical analysis.

Results: 1. Patients average age, 37–29 yrs old. Patients in 20s- more women. Patients in 30s and 40s- more men. No significant differences in remaining ages. Patients of onset age less than 20—women more than men. Patients of onset age from 20s to 30s—men more common. Patients of onset age over 40—no difference. 2. No family history difference between sexes. Onset age before 30-yrs-old—1.5 times higher family history. Patients under age 15—family history 2 times higher than patients who appeared at 30-yrs-old or more. 3. Average term of psoriasis: 115 months-men, 108 months-women. 4. Average term of corticosteroid use: 64 months-men, 69-women. No major differences for men/women. Most appeared region was leg for men/women. First appearing type—psoriasis nummularis for men, guttate psoriasis for women. Mixed type—psoriasis nummularis + guttate psoriasis. 5. Symptoms with psoriasis were itching most, next scaling- 6. 60% of patients didn't know why psoriasis appeared. Family history accounted for about 30%.

Conclusion: Women in 20s and men in 30s and 40s were shown much more. 20s to 40s account for majority—75.8%. If any family history, many cases occurred 30 yrs ago. Until visiting clinics, 9 years 2 months was average term of psoriasis. Average term of corticosteroid use was 5 years 5 months. Most appeared region: leg. Most cases not able to know cause of onset, thus, more research needed.

Disclosure of Interest: None to declare.

P075

Prevalence of musculoskeletal complaints and psoriatic arthritis in primary care patients with psoriasis

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Background: Over 25% of the new consultations in primary care is due to musculoskeletal complaints (MSC). In patient with psoriasis, the underlying diagnosis could be psoriatic arthritis (PsA). Prevalence figures of PsA in psoriasis patients vary widely (6–42%) and data in primary care is scarce.

Objective: To estimate the prevalence of MSC and PsA in primary care patients with psoriasis.

Methods: We conducted a cross-sectional study in adult primary care patients with psoriasis. Patients were identified from GP records by ICPC code S91 for psoriasis. Responding patients reporting pain in joints, entheses or the lower back were checked on eligibility by a telephone interview and invited for clinical evaluation. Ultrasonoghraphy (US) of the enthesis was performed if a patient had at least one tender enthesis (LEI/MASES) by an independent trained examiner. Patients were referred to a rheumatologist if clinical evaluation suggested the presence of arthritis or axial disease or ultrasonography of the enthesis showed positive Power Doppler(PD) signal. A PsA case was defined by opinion of the rheumatologist or fulfilling the CASPAR criteria with PD signal in an enthesis on US.

Results: 2,564 psoriasis (PsO) patients from 97 GPs were invited. Of the 1,673 responders (65.2%), 841 (50.3%) were willing to participate. 823 (32.1%) patients reported suffering from MSC of which eventually 524 were eligible and clinically evaluated. We identified 81 cases of PsA, of which 17 (21%) were newly diagnosed, leading to a prevalence of 3.2% (95%CI 2.5%>3.9%) among primary care psoriasis patients, assuming no additional cases of PsA among the non-responders. Besides these cases, we also identified 36 patients with enthesitis confirmed by ultrasound, which would increase the prevalence of PsA towards 4.6% (95% CI 3.8%>5.4%).

Conclusion: Among psoriasis patients in primary care the prevalence of PsA is estimated to be 3.2%, which would increase towards 4.6% if you take the enthesitis cases into account. We hereby assumed that no additional cases would be observed in the non-responders. The prevalence of MSC is estimated to be 32.1%, which is comparable with the prevalence in general population.

Disclosure of Interest: None to declare.

P076

Perception of drugs used in psoriasis management among dermatologists in India—Results of questionnaire based study

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Introduction: Psoriasis management is constantly evolving due to better understanding of the pathophysiology of psoriasis.Drugs used in psoriasis management range from topical therapy to systemic agents such as methotrexate, acitretin and cyclosporine up to biologic therapy such as Infliximab, Etanercept and Itolizumab in India.

Aim: To understand the treatment options which dermatologists prefer for psoriasis management.

Methods: A cross sectional survey of random sample of 70 dermatologists in India using a multiple choice questionnaire was performed. Results obtained were analysed.

Results: Methotrexate is still preferred as the first drug of choice by majority (85%) of dermatologists. Majority (53%) considered biologic therapy only when conventional systemic therapy fails to give desired response. Route of administration was considered to play an important role in deciding treatment options for patients with moderate to severe psoriasis. Combination therapy was preferred due to decreased chances of side effects. Greater interest towards newly available biologics was observed among dermatologists.

Conclusion: Variation in perceptions of the effectiveness and safety of systemic treatments was clearly observed. While methotrexate is still preferred, biologic therapy has begun to gain acceptance from dermatologists.

Disclosure of Interest: N. Sashidharan Employee of: Biocon Ltd; S. Kumar Employee of: Biocon Ltd; M. Saraswat Employee of: Biocon Ltd; M. Parikh Employee of: Biocon Ltd; D. Paul Employee of: Biocon Ltd.

GENETICS

P077

Polymorphism of IL-6 encoding gene in patients with psoriatic arthritis

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Introduction: IL-6 is a proinflammatory cytokine involved in the development of psoriatic arthritis (PsA).

Objectives: The present study aimed to determine the possible association between the *IL-6* gene polymorphism and PsA susceptibility, progression of the disease and response to therapy with TNF-α inhibitors.

Methods: For this purpose 71 patients and 126 healthy individuals were investigated and genotyped for the *IL-6* (C-174G) alleles by real-time PCR amplifications with the use of LightSNiP assays. In addition, in 52 patients IL-6 and CRP (IL-6 read out protein) serum levels were assessed and analyzed in relation to clinical data and IL-6 allelic variants.

Results: Analysis of the distributions of the IL-6 genotypes showed a significant prevalence of the *IL-6* heterozygosity when compared to the *GG* homozygous genotype carriers (OR = 2.05, $P = 0.052$). Polyarthritis was less frequent among the *GG* homozygous patients than those with the *C* allele ($P = 0.083$). The *IL-6* polymorphism correlated with the IL-6 and CRP serum levels. The higher serum levels were observed for patients with the *IL-6 G* allele ($P = 0.026$ and $P = 0.032$ for IL-6 and CRP levels, respectively). Majority of patients carrying this *IL-6 G* allele were worse responders to methotrexate therapy and were subjected to the anti-TNF-α treatment ($P = 0.046$). Moreover, only IL-6 heterozygous individuals belonged to patients that had to change one anti-TNF-α inhibitor (ineffective) to another one ($P = 0.008$).

Conclusions: These results imply, that the *IL-6* polymorphism is associated with PsA susceptibility and progression of PsA as well as IL-6 and CRP serum levels in patients with this disease.

Disclosure of Interest: None to declare.

P078

Genetic variations within genes coding IL-12, IL-17 and IL-33 and their serum levels in patients with psoriatic arthritis—preliminary results

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Introduction: Interleukin (IL)—12, IL-17A, IL-17F and IL-33 belong to the family of cytokines involved in systemic inflammation playing a key role in pathogenesis of psoriasis (PSO) and psoriatic arthritis (PsA).

Objectives: The present study aimed to assess the associations between polymorphisms within respective genes, serum levels of these cytokines and predisposition to PsA, activity of the disease and response to therapy with TNF- blocking agents.

Methods: Seventy-one PsA patients (diagnosed by the criteria recommended by CASPAR group) and 126 healthy individuals were typed for the *IL-12B* (rs3212227, rs6887695), *IL-17A* (rs2275913), *IL-17F* (rs763780) and *IL-33* (rs7044343) polymorphisms. Cytokine serum levels were assessed in 52 patients by ELISA. Disease Activity Score was measured (swollen and tender joints, ESR, CRP) in addition to BASDAI, BASFI, VAS, and PASI scores.

Results: The *GG* homozygosity within the *IL-17A* and *IL-12B* (rs6887695) genes strongly tended to be correlated with susceptibility to PsA (OR = 1.768, $P = 0.092$ and OR = 1.955, $P = 0.056$, respectively). Patients with the *AA* homozygous genotype of the *IL-12B* (rs3212227) more frequently presented with polyarthritis than patients lacking this genotype ($P = 0.070$). No other relationship was observed between polymorphisms and disease activity. In addition, IL-33 serum levels were higher in patients with the *IL-33 C* allele ($P = 0.087$). None of the polymorphic variants was found to affect the response to anti-TNF treatment.

Conclusions: In conclusion, the results of the present study suggest that *IL-17F* and *IL-12B* polymorphisms may be of prognostic value in patients with PsA.

Disclosure of Interest: None to declare.

P079

HLA-Cw6 polymorphisms may help predict response to biologic therapy in patients with chronic plaque psoriasis

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Introduction: To-date response to biologics has been based on clinical observation and no genetics markers have been found to predict response to treatment. In 1993 our research suggested that HLA-Cw6 was a susceptibility gene for psoriasis. Our data also suggested that HLA-Cw6 was linked to both the age of onset of psoriasis as well as the need for patients to require photo or systemic therapy for psoriasis treatment. With the introduction of biologic therapy we now have the tools we need to treat this severe and relentless disease. Biologics offer us not only improved therapeutic benefit but a much more favorable safety profile. As there is variability in the response of patients to biologics single-nucleotide polymorphisms (SMP) that may identify responders and non-responders would be of benefit. Polymorphisms of the macrophage migratory and inhibitory factor gene (173 G/C) are associated with response to glucocorticoids in JIA asthma and nephrotic syndrome. (Leila E. D'Urbano *et al*., ARC 2006) Recent polymorphism in the tumor necrosis factor-α gene (308 A/G polymorphism) may predict treatment response to etanercept in patients with rheumatoid arthritis. Patients with RA ad 308 G/G TNF-α genotype tend to respond better to etanercept therapy. In the Newfoundland and Labrador founder population not only is HLA-Cw6 a susceptibility gene but preliminary data suggest it may be able to predict response to biologics.

Objective: To study HLA Cw6 and its association to biological therapy response.

Methods: Using the Newfoundland and Labrador founder population we have genotyped 91 patients who have been treated with biologics and then classified the patients into 2 groups (patients with a clinical response to biologics and patients that have not had a clinical response to biologics and have discontinued treatment).

Results: Preliminary results suggested that patients who are positive for HLA-Cw6 respond to biologics and those patients negative for HLA-Cw6 may fail treatment.

Conclusions: This study demonstrates that the use of the Newfoundland and Labrador founder population and HLA-Cw6 status may be helpful in predicting response to certain biologics.

Disclosure of Interest: None to declare.

P080

Serum level of IL-23 and IL-23R polymorphisms in patients with psoriatic arthritis

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Introduction: Interleukin (IL)—23 is one of the of cytokines involved in systemic inflammation. Interaction between this cytokine and its receptor (IL-23R) that plays an important role in pathogenesis of psoriatic arthritis (PsA).

Objectives: The present study aimed to assess the associations between polymorphisms within gene coding IL-23R, IL-23 serum levels and disease activity in patients with PsA.

Methods: Fifty-two PsA patients (diagnosed by the criteria recommended by CASPAR group) were genotyped for the *IL-23R* (rs11209026 and rs7530511) polymorphisms. The nuclear factor kappa (*NF-kB1* (rs28362491; *ins/del*)) polymorphism (associated with the promoter activity of this gene and cytokine gene expressions, including IL-23) was also analyzed in PsA patients group. IL-23 serum levels were assessed by ELISA in patients with PsA, and for comparison, 10 healthy individuals. These laboratory data were further related with clinical characteristics of the patients. Disease Activity Score was measured (swollen and tender joints, ESR, CRP) in addition to BASDAI, BASFI, VAS, and PASI scores.

Results: Significantly ($P<0.05$) elevated levels of IL-23 cytokine were observed in PsA patients (126.5 pg/ml) when compared to control group (24.9 pg/ml). Moreover, IL-23 serum levels were associated with the *IL-23R* rs7530511 polymorphism. Patients carrying the *IL-23R T* allele characterized with higher concentrations of IL-23 in serum (299.1 versus 86.8, $P<0.05$). Interestingly, patients with the *IL-23R T* allele were also more frequently carrying the *ins/ins* homozygous *NF-kB1* genotype (associated with a better promoter activity and higher expression of cytokines) (7/17 versus 4/34, distribution of the *T* allele among *ins/ins* versus *del* allele positive patients, $P=0.03$). No association was found between for IL-23 levels or *IL-23R* polymorphisms and disease activity.

Conclusions: Patients with PsA characterize with higher serum levels of IL-23 than patients with RA and healthy individuals. IL-23 concentrations in serum of PsA patients are associated with the polymorphism (rs7530511) of IL-23 receptor encoding gene.

Disclosure of Interest: None to declare.

HEALTH ECONOMICS AND HEALTH POLICIES

P082

Treatment patterns and healthcare resource utilisation (HCRU) among patients with psoriatic disease in a large national claims database

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Background: Despite advances in psoriatic arthritis (PsA) and psoriasis (PsO) treatment (tx) guidelines, many pts remain untreated or under-treated.

Objectives: To describe tx patterns and HCRU in US pts with PsA only or PsA and PsO (PsA/PsO).

Methods: Adult pts had ⩾2 outpatient/1 inpatient visit for psoriatic disease (ICD-9: 696.1/696.0) in the Truven MarketScan Claims Database (2009–2014) with continuous enrolment ⩾6 months before and ⩾12 months after diagnosis (index: Day 0). Initial (⩽30 days post-index) tx was classified as monotherapy (monotx) or combination; combination tx was defined hierarchically as biologics + other (B), conventional systemic + non-biologic (CS), phototherapy/topical + non-biologic/non-conventional systemic (PT). Unadjusted PsA- and PsA/PsO-related HCRU and costs were assessed 1-year post-index.

Results: Of 7,512 PsA pts, 46.7% were initially treated. Initial monotx (32.3%) was 9.4% biologic, 9.3% conventional systemic, 2.6% topical and 11.1% NSAIDs. Initial combination tx was 38.9% B and 21.6% CS. Of 10226 PsA/PsO pts, 46.0% were initially treated. Initial monotx (25.6%) was 5.1% biologic, 3.8% conventional systemic, 9.4% topical, 0.9% phototherapy and 6.4% NSAIDs. Initial combination tx was 38.3% B, 22.4% CS and 0.7% PT. Of pts who did not receive initial tx, 63% (PsA) and 59% (PsA/PsO) remained untreated 181–365 days post-index. Total mean disease-related costs for PsA and PsA/PsO were $34678 and $40808 (based on pts with available cost data). Pharmacy prescriptions and outpatient office visits (table) and costs were higher in pts with initial tx versus no initial tx ($P<0.0001$) in both groups.

Conclusion: Over half of pts did not receive initial tx; initial tx was associated with increased HCRU versus no initial tx.

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[P082] Table 1

HCRU Mean # of events (SD) (***$P<0.0001$ versus initial tx)	PsA Initial tx ($N=3510$)	PsA No initial tx ($N=4002$)	PsA/PsO Initial tx ($N=4705$)	PsA/PsO No initial tx ($N=5521$)
Pharmacy prescriptions	10.6 (6.6)	5.4 (4.4)***	10.1 (6.8)	5.9 (4.6)***
Inpatient visits	1.1 (0.2)	1.1 (0.4)	1.1 (0.3)	1.1 (0.4)
Outpatient office visits	3.8 (2.3)	3.3 (2.2)***	4.9 (3.5)	4.4 (3.0)***
Emergency room visits	2.3 (0.6)	2 (0.0)	2.8 (1.5)	2.3 (0.5)

P081

Increased frequency in the HLA DR*04 alleles in Mexican patients with psoriasis

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Introduction: There is a genetic predisposition that allows the development of psoriasis, which is associated with several genes, specially Cw6. This explains its clinical variability; however, the association with HLA DR has not been plainly studied. HLA-DR alleles are related to the development of inflammatory chronic illnesses in Mexican patients.

Objective: The aim of this study is to know the frecuency of HLA DR haplotypes in Mexican patients with psoriasis, and compare with healthy Mexican controls.

Method: With the information and authorization by the Hospital Ethics and Research Committee and the previous knowledge and signed authorization of the psoriasis patients, we took 5ml of blood to 22 patients in order to extract DNA genomic. Then we identified the polymorphisms of the locus HLA DR by PCR thecnic using a TEPNEL LUMINEX SSO kit. The results of the genetic frequencies were compared with the data of 198 healthy subjects.

Results: The results were analyzed with square chi. A significant statistically increment of the HLA-DR*04 in patients with psoriasis compared with the controls. The values obtained are $P=0.003$, OR 2.6, IC 95% of 1.2–5.5.

Conclusions: HLA DR*04 haplotype is increased in Mexican patients with psoriasis. This haplotype could be related with the susceptibility of Mexicans to acquire psoriasis, as it has been demonstrated for other inflammatory diseases.

Disclosure of Interest: None to declare.

P083

Incremental costs per patient for psoriasis and psoriatic arthritis in a population-based referent cohort: Are there clear links to psoriasis morbidity?

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Introduction: There is need for more data on resource use and costs for patients with psoriasis alone (PSO) and psoriasis patients with psoriatic arthritis (PsA) from a population–based perspective, especially after the introduction of biological treatment for these groups.

Objectives: To study incremental societal costs for PSO/PsA patients versus referents free from PSO/PsA, and to estimate costs attributable to specific PSO/PsA problems.

Methods: Patients were identified by ICD-10 codes related to PSO/PsA using data from 1998 to 2007 in a regional healthcare register covering all healthcare use for approximately 1.2 million people. For each PSO/PsA patient, three population-based referents were selected. Data on primary care, secondary outpatient care, inpatient care, drugs and work loss were analyzed for years 2008–2011. The mean annual cost per patient was adjusted for cases and referents exiting the study. The human capital method was used to value work loss. We used a societal perspective and expressed costs in Euros (2011 price level).

Results: We identified 15,283 patients who fulfilled the inclusion criteria for PSO ($n=12,562$, 50% women, mean age (SD) 52 (20)) or PsA ($n=2,721$, 56% women, mean age 54 (16)) and included 45,849 referents. Mean annual societal cost for patients with PSO/PsA exceeded the cost for referents by 56%, €11,146 versus €7132 ($P<0.0001$). The cost was 84% higher for PsA compared to PSO, €17,853 versus €9,693 ($P<0.0001$). Costs due to work loss represented the largest share of total costs in all groups. Almost 25% of the total costs were attributable to inpatient care for PSO patients and 12% for PsA patients. Costs for biological DMARDs represented 10% of the total costs for PsA and 1.5% for PSO. In PsA, drug costs accounted for 44%, and physician costs accounted for 11% of the costs attributable to specific PSO/PsA problems. These figures were less for PSO.

Conclusion: The costs were highest for PsA, mainly due to work loss and biological treatment. A small fraction of the costs were directly attributable to PSO/PsA problems, indicating an increased morbidity in these patients that needs to be further studied.

Disclosure of Interest: None to declare.

INTERESTING CLINICAL CASES

P084

Psoriatic arthritis with MALT lymphoma- a case report

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Case Report: A 60-year-old with a history of psoriasis and gout developed flu-like symptoms and generalized arthralgias prompting an ER visit. Blood work revealed pancytopenia, transaminitis, and acute renal injury. Peripheral blood smear, imaging studies, and microbiological evaluation were unrevealing, and he was referred to our center. Psoriatric arthritis was confirmed by typical joint involvement with classic dermatological findings. Repeat rheumatologic, infectious, and paraneoplastic work-up was unrevealing. His symptomatology persisted over the ensuing months, when he developed a diffuse, right-sided parotid gland swelling. Biopsy revealed malignant cells consistent with a low-grade extra nodal marginal zone (MALT) lymphoma. The patient received therapy with rituximab with favorable response.
Discussion: Associations between autoimmune conditions and lymphoproliferative disorders have been the focus of multiple studies and reports. Anderson *et al.* demonstrated an association between Non-Hodgkin lymphoma and autoimmune conditions like rheumatoid arthritis, Sjogrens syndrome (SS), and systemic lupus erythematous (SLE).[1] MALT lymphoma has also been linked with SLE and SS.[2] In patients with psoriasis, it has been hypothesized that chronic inflammation, deficient immune surveillance, genetic susceptibility, and treatment effects may lead to lymphoproliferative disorders, primarily T-cell lymphomas.[3] To our knowledge, this is the first reported case of MALT lymphoma developing in a patient with psoriatic arthritis. Rituximab, a monoclonal antibody directed against B-cell specific antigen CD20, is effective for B-cell lymphomas, including MALT lymphoma.
Disclosure of Interest: None to declare.
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P085

Cardiac tamponade as a complication of anti-TNF therapy in psoriatic arthritis

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Introduction: Patients with psoriatic arthritis respond well to therapy with anti-TNF. Auto-antibody formation and autoimmune disease have been described in patients treated with anti-TNF.
Objective: To describe a case of psoriatic arthritis that developed cardiac tamponade along with lupus serology while on therapy with Infliximab.
Methods: 42 year-old male with history of psoriasis and psoriatic arthritis was well controlled on Infliximab initiated 4 months prior to this presentation. Over a course of 4 days he developed dyspnea with minimal exertion along with significant lower extremities edema. He had evidence of large pericardial effusion with tamponade physiology on subsequent ECHO that required a pericardial window. A 650 cc pericardial fluid was removed. Infectious etiology was ruled out. Further work up was remarkable for positive ANA at a titer 1:640 (prior testing was negative by same method of ANA detection) and his anti-dsDNA was also positive at a titer 125 by Crithidia luciliae assay. His symptoms responded to withdrawal of Infliximab and addition of steroids and Plaquenil.
Subsequently his psoriatic arthritis was poorly controlled and he was initiated on Humira with excellent clinical response and no recurrence of his serositis at 2 years of follow up.
Results: Pericardial involvement is common in SLE patients and it was described in drug induced lupus including lupus-like syndrome induced by anti-TNF. Pericardial tamponade is a very rare manifestation in SLE and it has not been described in the literature as a manifestation of lupus-like syndrome induced by anti-TNF.
Conclusions: Cardiac tamponade can be a manifestation of anti-TNF induced lupus-like syndrome in psoriatic arthritis patients treated with anti-TNF.
Disclosure of Interest: None to declare.

P086

Psoriasis and vitiligo in same patient: an unique concurrence

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Background: Although association between psoriasis and vitiligo is well known, the pathogenetic association between the two is still elusive. Autoimmunity, common neuropeptides and koebners phenomenon have been implicated to explain the pathological link. Very few case series have been reported so far dealing with appearance of vitiligo and psoriasis in the same patient.
Objective: To study the prevalence of psoriasis and vitiligo co-localization in the same patient.
Methods: Retrospective analyses of psoriasis patients records seen between January 2011 and December 2014 for the concurrent presence of vitiligo.
Results: Overall 900 psoriasis patients were analysed, of which only 5 patients had concurrent vitiligo; 4 females and 1 male. The mean age of study cohort was 32 ± 8.5 years(9–80 years), mean age of psoriasis onset was 25 ± 2.6years and of vitiligo 10.3 ± 3.5 years. Three patients had vitiligo vulgaris, acrofacial and focal vitiligo was noted in 1 patient each. Four patients had psoriasis vulgaris and 1 guttate psoriasis. Psoriasis lesions confined to lesions of vitiligo were found in only 2 patients (1 patient each with psoriasis vulgaris and guttate psoriasis) while remaining had lesions distributed widely independent of vitiligo. Onset of vitiligo preceded psoriasis in 4 patients.
Conclusions: Our results emphasizes that psoriasis need not selectively involve vitiliginous lesions. More molecular studies are required to unfold the enigmatous pathogenesis involved in the concomitant appearance of both these disorders.
Disclosure of Interest: None to declare.

P088

A case of CIN 1 with guttate psoriasis

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Introduction : Psoriasis is universal in occurrence, its prevalence in different population group varies from 0.1 to 11.8%.[1] The root cause is unknown. An interesting case report of small plaque psoriasis associated with CIN type 1 is described here.
Objectives : The case report was an incidental finding of clearance of small plaque psoriasis lesions following treatment of CIN type 1.
Method: A healthy 48 year old female patient reported with seborrhoea scalp and lichenified lesions on various parts of body including pals & soles. All investigations were within normal limits, including VDRL in serial dilution, viral markers, liver & kidney functions, lipid profile , complete haemogram, & RA factor. Histopathology was conclusive with Psoriasis. BSA was >30%, patient was intolerant to oral & injectable methotrexate and to oral Cyclosporine. Injecatble Etanercept 50 mg twice a week was planned along with topical emollients. She was sent for routine health check up where on PAP smear & following histopathology confirmed CIN type 1. The patient was treated surgically for CIN type 1. Biologic therapy was deferred till her treatment for CIN type 1 was over.
Result: Within 4 weeks of hysterectomy all lesions of small plaque psoriasis cleared without any active treatment for skin lesions except emollients. After 3 years of regular follow up the patient has not yet developed any lesion suggestive of relapse of psoriasis. Her gynaecological condition is also stable.
Conclusion : This is probably the 1st case reported of development of small plaque psoriasis in a middle aged female patient following CIN and its self clearance after hysterectomy & complete treatment for CIN.
Disclosure of Interest: None to declare.
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PATHOPHYSIOLOGY AND IMMUNOBIOLOGY

P089

IL-1 and IL-36 are the dominant cytokines in generalized pustular psoriasis

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Introduction: Generalized pustular psoriasis (GPP) is a rare debilitating and often life-threatening, inflammatory disease characterized by episodic infiltration of neutrophils into the skin, pustule development, and systemic inflammation. This condition can manifest in the presence or absence of chronic plaque psoriasis (CPP). Current treatments are unsatisfactory and a better understanding the pathogenesis of GPP may yield new therapeutic approaches.
Objectives: To assess the pathophysiological differences between GPP and CPP.
Methods: We analyzed archived formalin-fixed paraffin-embedded biopsies of confirmed GPP ($n=20$) and CPP ($n=12$) cases and healthy control ($n=12$) skin using Affymetrix Human Gene ST 2.1 arrays, confirmed findings using qRT-PCR and immunohistochemistry.
Results: Gene expression analysis revealed that compared with healthy skin, GPP and CCP lesions yielded 861 and 779 differentially expressed genes (DEGs, >2-fold change, $P<0.05$) respectively, with 269 of the upregulated transcripts common to both diseases. Examining the DEGs, qRT-PCR showed significantly higher expression of *IL36A* (3-fold, $P=0.015$) and *IL36G* (4-fold, $P=0.05$) in GPP compared with CPP; however expression of the receptor antagonist (*IL36RN*) was equivalent in the 2 diseases. Likewise, *IL1B* was 11 times more abundant in GPP than CPP ($P=0.005$), with equivalent expression of *IL1RN*. This was accompanied by increases in neutrophil chemokines *CXCL1, CXCL2* and *IL8* (15-, 3-, and 20-fold greater mRNA expression in GPP than CPP respectively, $P<0.05$, all). IHC confirmed higher IL-36α, IL-36γ, IL-1β and neutrophil abundance in GPP lesions compared with CPP. Suggesting a departure from typical Th1/Th17 pathophysiology, *IL23A, IL17A, IFNG, CXCL9, CXCL10* and *MX1* expression were found to be significantly lower in GPP compared to CPP ($P<0.01$ all).
Conclusions: Our findings indicate sustained activation of the IL-36 and IL-1 systems in GPP, which drive neutrophil infiltration. These data may have major therapeutic implications as they suggest that the IL-1 and IL-36 are the main drivers of disease pathology in GPP, and question the contribution of IL-17 and/or IFN-γ in GPP pathogenesis.
Disclosure of Interest: None to declare.

P090

Regulation of IL-10 Production, an anti-inflammatory feed-back of Human defensin-2 in psoriasis?

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Introduction: Human defensin-2 (hBD2) belongs to the family of antimicrobial peptides that are believed to be important immune activators. It has been demonstrated to be expressed at high levels in psoriatic lesions. Besides its known pro-inflammatory role in autoimmune, whether hBD2 has any anti-inflammatory effects has not been established.
Objectives: To investigate the impacts of hBD2 on the expression of IL-10, an anti-inflammatory cytokine, in psoriasis.
Methods: Fifteen psoriatic patients were inrolled and their peripheral blood mononuclear cells (PBMCs) were isolated. PBMCs were stimulated with hBD2 or IL-10 of different concentrations. The cytokines were measured with ELISA kits.
Results: We found that hBD2 increased IL-2, IL-10 expressions in PBMCs. These effects were more obvious for hBD2 of higher concentrations.On the other hand, IL-10 downregulated the expression of hBD2.
Conclusions: The results of this small pilot study suggested the dual-directional regulation of hBD2 in psoriasis. hBD2 of high concentration induced anti-inflammatory IL-10, which showed a feed-back suppression on the overpression of hBD2.
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Disclosure of Interest: None to declare.

P091

Regulation of FOXP3 + Regulatory T cells by leptin in psoriasis

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Introduction: Leptin is a peptide hormone involved in the regulation of energy intake and obesity. It has been recently shown to induce proinflammatory cytokines. More recently, leptin has been suggested to be an important regulator of Th1-cell dependent autoimmune diseases, including ankylosiag spondylitis and multiple sclerosis. There is a close relationship between psoriasis and obesity, hypermetabolism. In psoriasis, serum leptin levels have been identified to be significantly higher in patients with severe ones than patients with mild-moderate ones and controls. It has been suggested as a severity marker and chronicity cofactor in psoriasis. However, the mechanism by which leptin regulates the immune network in psoriasis has not been identified.
Objectives: To investigate the effects of leptin on FOXP3 + Regulatory T cells in psoriasis.
Methods: Fifteen psoriatic patients and 5 healthy controls were included into this study. The methods used in this study included immunohistochemistry, mouse models of starvation and high-fat diets, Western blot, and flow cytometry.
Results: We found that, besides the epidermis, there were intense leptin expressions in the infiltrated inflammatory cells in psoriatic dermis by immunohistochemistry. There was a direct correlation between leptin levels and FOXP3 + Regulatory T cells. We confirmed their relationship in mouse models by starvation and high-fat diets. We also confirmed the expression of leptin receptors on FOXP3 + Regulatory T cells. Next, we found that neutralization of leptin antibody could rescue the attenuation of FOXP3 + Regulatory T cells by leptin. We identified STAT3 pathway was the main pathway which mediated the effects of leptin on FOXP3 + Regulatory T cells in psoriasis. The inhibitor of this pathway could rescue the attenuation of FOXP3 + Regulatory T cells by leptin.
Conclusions: Our study supported the view that leptin might be a new therapeutic target in psoriasis. Further studies by mouse model of psoriasis are warranted to clarify this possibility.
Grant support: This work was partly supported by National Natural Science Foundation of China (No. 81371729).
Disclosure of Interest: None to declare.

P092

Evaluation of Th17 cells and associated cytokines in patients with psoriasis

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Background: T helper cells 17 (Th17) cells have recently emerged as important player in the pathogenesis of psoriasis. The Th17 immune effector pathway is mediator of inflammation in patients with psoriasis, both in peripheral circulation and in skin lesions.[1,2]
Objective: To determine the frequency of Th17 cells in peripheral blood of patients with psoriasis and to analyze its relation with disease severity.
Methods: This was a prospective study comprising 34 patients with psoriasis vulgaris and 24 healthy controls. Using 3-color flow cytometry, circulating Th17 and Th1 cells were quantified in untreated patients with psoriasis and healthy controls. In the serum collected from patients with psoriasis and healthy controls, the concentrations of IL17A and IL23 were examined by ELISA methods. Severity of psoriasis was assessed by means of PASI score.
Results: Increased frequencies of CD4 + ve IL17A + ve T cells were seen in peripheral blood of patients with psoriasis vulgaris ($P = <0.002$) but it did not correlate with age at onset, disease severity as well as duration of the disease. Serum IL17A and IL23 concentrations were elevated in patients with psoriasis as compared to controls but the figures were not statistically significant.
Conclusions: Increased serum levels of circulating inflammatory Th17 cells may contribute to cutaneous pathology as well as inflammatory process that is hallmark of patients suffering from psoriasis vulgaris.
Disclosure of Interest: None to declare.
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P093

A study of the number of circulating CD4 + CD25 + Foxp3 + regulatory T cells and CD4 + CD25- Foxp3 + T cells in psoriasis

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Introduction: Regulatory T cells (Treg) are able to inhibit the immunological response and to maintain the cutaneous immunological homeostasis, thus preventing autoimmunity against itself. In several studies, the importance of CD4 + CD25 + Foxp3 + Treg in psoriasis has examined in the peripheral blood of patients. But, limited studies on Treg are available and give conflicting results. Recently, CD4 + CD25-Foxp3 + T cells have been intrigued as peripheral reservoir of CD4 + CD25 + Foxp3 + Treg.
Objectives: To investigate differences in the CD4 + CD25 + Foxp3 + Treg and CD4 + CD25-Foxp3 + T cells count between patients with psoriasis and normal controls.
Methods: For phenotypic analysis, proportions and absolute cell numbers of CD4 + CD25 + Foxp3 + Treg and CD4 + CD25-Foxp3 + T cells in peripheral blood were examined by flow cytometry. The correlation between CD4 + CD25 + Foxp3 + Treg count and the other parameters, such as age of onset, disease duration, BSA, PASI score and clinical stage was also analyzed.
Results: Although CD4 + CD25 + Foxp3 + Treg count was increased slightly and the number of CD4 + CD25-Foxp3 + T cells was slightly decreased in psoriasis patients compared with controls, there were not statistically significant (5.27 ± 2.60 versus 4.70 ± 1.35, $P > 0.05$, 1.56 ± 1.07 versus 1.93 ± 1.08, $P > 0.05$). CD4 + CD25 + Foxp3 + Treg count was not correlated with any parameter except clinical stage of psoriasis. Mean ± numbers of CD4 + CD25 + Foxp3 + Treg in stable phase was higher than in progressive phase (7.26 ± 2.58 versus 4.35 ± 2.10, $P < 0.05$). CD4 + CD25-Foxp3 + T cell count did not show any significant correlation with all parameters ($P > 0.05$).
Conclusions: These findings suggest that only CD4 + CD25 + Foxp3 + Treg count is insufficient to explain the pathogenesis and severity of psoriasis. But a decrease of circulating CD4 + CD25 + Foxp3 + Treg is likely to correlate with aggravation of psoriasis.
Disclosure of Interest: None to declare.

P095

MiR-146a, a microRNA overexpressed in psoriasis, is a potent regulator of IL-1β − induced inflammatory responses in keratinocytes

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Introduction: MicroRNAs are short, endogenous non-coding RNAs that regulate gene expression at the post-transcriptional level. We and others have previously shown that a set of microRNAs is deregulated in psoriasis skin lesions.
Objectives: The aim of this study was to investigate the expression and function of microRNA-146a (miR-146a) in psoriasis.
Methods: MiR-146a expression was analyzed by qPCR and in situ hybridization. MiR-146a levels were modulated in primary human keratinocytes by transfection of synthetic miR-146a precursor, or specific miR-146a inhibitor. Neutrophil migration was assessed by chemotaxis assay. Transcripts regulated by miR-146a were identified by transcriptomic profiling.
Results: We found that miR-146a is up-regulated in lesional, but not in non-lesional skin of psoriasis patients. Both epidermal keratinocytes and dermal infiltrating cells contribute to the overexpression of miR-146a in psoriasis, as evidenced by *in situ* hybridization. We identified IL-1β, a cytokine overexpressed in psoriasis skin, as an inducer of miR-146a in keratinocytes. A single stimulation with IL-1β resulted in long-lasting up-regulation of miR-146a, contrasting to the rapid and transient expression of inflammatory mediators (eg IL-8, CCL20, TNF-α) in keratinocytes. Overexpression of miR-146a suppressed the baseline and IL-1β–induced production of IL-8, CCL20 and TNF-α. Moreover, overexpression of miR-146a in keratinocytes resulted in decreased chemotactic attraction of neutrophils. By contrast, inhibition of endogenous miR-146a enhanced the baseline and IL1β–induced production of inflammatory mediators. Transcriptomic profiling revealed that miR-146a suppressed the expression of a large number of immune-related genes in keratinocytes, including cytokines, chemokines and components of immune-related signal transduction pathways.
Conclusions: Altogether, our results identify miR-146a as a negative regulator of the IL-1 β − induced inflammatory response of keratinocytes. Its overexpression in keratinocytes of psoriasis lesions may serve as a negative feedback to control inflammation.
Disclosure of Interest: None to declare.

P096

Psoriasin (S100A7) regulates markers of epidermal differentiation

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Introduction: Psoriasis is characterized by epidermal hyperproliferation and a disturbed differentiation process. The maturation pathway of keratinocytes in psoriatic lesions differs from that of the normal epidermis and an altered sequence of expression of differentiation markers has been described in psoriasis. Psoriasin is highly expressed in psoriatic keratinocytes and in several other conditions that display abnormal cell differentiation.
Objective: The aim of this study was to investigate the involvement of psoriasin in keratinocyte differentiation.
Methods: The expression of psoriasin in psoriatic skin was determined using immunohistochemistry. The effect of keratinocyte differentiation on psoriasin expression was investigated by culturing human epidermal keratinocytes (HEKn) under differentiation-inducing conditions and the involved signalling pathways were studied by treating the cells with specific inhibitors. To determine the role of psoriasin in inducing differentiation, psoriasin expression was downregulated using siRNA.
Results: We found a marked psoriasin expression in the psoriatic epidermis. The expression formed a gradient, ranging from a weak staining in the basal layer to an intense staining in the more differentiated suprabasal layers. The induction of differentiation using $CaCl_2$, PMA, suspension culture and confluence culture gave rise to morphological changes, an upregulation of the differentiation marker involucrin and an increased production of psoriasin. Inhibition of the PKC pathway reduced the expression of both psoriasin and involucrin. Treatment with $CaCl_2$ also triggered the induction of the differentiation markers filaggrin, desmoglein 1, desmocollin 1, transglutaminase 1 and CD24. Downregulation of psoriasin using siRNA resulted in a decreased expression of involucrin, desmoglein 1, translutaminase 1 and CD24, suggesting that psoriasin may be involved in the regulation of these markers.
Conclusion: These data suggest that psoriasin upon upregulation in response to differentiation-inducing stimuli in turn may regulate the expression of several differentiation markers and may influence the keratinocyte differentiation process.
Disclosure of Interest: None to declare.

P097

IL-17C, TNFα and IL-36 compensate for loss of IL-6 and identify novel signals facilitating the transition between uninvolved and involved psoriasis skin

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Introduction: IL-17C is proinflammatory and highly expressed in lesional psoriasis skin. Mice overexpressing IL-17C in keratinocytes (KC; K5-IL-17C) develop a skin disease phenocopying human psoriasis, including well-demarcated uninvolved (PN) and involved (PP) skin. PN skin from K5-IL-17C mice has increased IL-6 and TNFα protein (~2.5-fold; $P < 0.05$) versus controls and these increase ~10-fold in PP skin ($P < 0.05$) suggesting a role for these molecules in the PN-PP transition.
Objectives: Demonstrate that IL-6-TNFα-IL-17C synergy contributes to the PN-PP transition and disease severity.
Methods: K5-IL-17C and IL-6KO mice were mated and skin inflammation examined. Primary human KCs were stimulated with IL-17C, IL-6 and TNFα and key psoriasis signature genes measured.
Results: Less severe skin inflammation developed in K5-IL-17C-IL-6KO mice versus K5-IL-17C mice between 10–12 wks of age evidenced by less body surface area involvement ($P < 0.05$; $n = 8$/grp); this difference was eliminated by 14 wks of age suggesting that cellular and molecular events within the skin compensate for IL-6 absence and promote the PN-PP transition. PN skin of 10 and 14 wk old K5-IL-17C-IL-6KO and K5-IL-17C mice was compared and decreases in acanthosis, angiogenesis, skin $CD4^+$, $CD8^+$ and $F4/80^+$ cells were found at 10 wks (all $P < 0.04$) and were abrogated by 14 wks. Serum TNFα and cutaneous IL-17C, IL-36β and IL-36γ were also reduced (~2–5-fold; $P < 0.05$) at 10 wks yet increased significantly at 14 wks, as did skin-TNFα (3-fold; $P = 0.003$) perhaps compensating for the lack of IL-6. To examine the importance of IL-6, primary adult human KCs were stimulated with IL-6 and significant increases in TNFα, IL-17C, IL-36β and IL-36γ ($n = 6$; $P < 0.05$) were observed and increased further when co-stimulated with IL-17C ± TNFα. Finally, PN skin of K5-IL-17C-IL-6KO mice reconstituted with intradermal IL-6 every other day between 8–10 wks of age had their skin phenotype return to levels similar to K5-IL-17C mice.
Conclusions: These data suggest that IL-17C, TNFα and IL-36 can compensate for loss of IL-6 and identify novel signals facilitating the PN-PP transition in psoriasis skin.
Disclosure of Interest: None to declare.

P098

Antibodies towards high density lipoproteins components in patients with psoriasis

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Introduction: Psoriasis is a chronic inflammatory immune disorder targeting mostly the skin. Amongst other complications and comorbidities, these patients have an increased burden of subclinical atherosclerosis and endothelial dysfunction and their relative risk for cardiovascular events is increased by 25%. Despite the recognition of the presence of multiple mechanisms, this increased risk is not fully understood. High-density lipoproteins (HDL) play an important role in the prevention of atherosclerosis. Our group has identified the presence of anti-HDL (aHDL) antibodies in patients with autoimmune diseases, and associated them with modifications in the anti-oxidant and anti-inflammatory functions of HDL.

Objectives: This study was undertaken to determine the presence of antibodies directed against different components of the HDL complex and to establish a possible relationship between these antibodies and disease severity in patients with psoriasis.

Methods: Sixty patients were compared with an age and sex-matched control group. Epidemiologic and clinical data were recorded. IgG aHDL and aApo A-I antibodies were assessed by ELISA. Plasma lipid profile was determined by standard enzymatic techniques. Apolipoprotein A-I and E were measured by immunoturbidimetric immunoassay.

Results: Patients with psoriasis had higher titres of aHDL ($P<0.0001$) and aApo A-I antibodies ($P<0.0001$), lower HDLc ($P=0.01$) and increased levels of ApoE ($P=0.002$). aHDL levels directly correlated with aApo A-I ($r=0.46$, $P=0.0003$). The titres of aHDL antibodies were associated with an increase in Psoriasis Area and Severity Index (PASI) but not with disease duration.

Conclusions: This is the first report showing the presence of aHDL and aApo A-I antibodies in patients with psoriasis. These antibodies were associated with an increased disease severity and may contribute to the pathogenesis of atherosclerosis in this context.

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PSORIASIS AND PSORIATIC ARTHRITIS RELATIONSHIP

P100

Concordance of the PASE Questionnaire (Psoriatic Arthritis Screening Evaluation) for the screening and assessment of clinical practice in psoriatic arthritis

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Objectives: To assess the concordance of the PASE questionnaire in the screening of psoriatic arthritis (PsA) in psoriasis (PSO) patients in clinical practice and its relationship with the PsA activity measures.

Methods: During 2014 the Dermatology Department has referred all patients with PSO, consecutively, to the Rheumatology Department to evaluate the utility of screening questionnaires PASE for the diagnosis of PsA and to detect articular activity. A score >47 in questionnaire PASS has been shown as a good 'cut-off' for the suspiction of PsA. Dermatology performed the cutaneous assessment and the PASE. Rheumatology performed the articular assessment, CASPAR criteria completion, PsA diagnosis, DAS28 and BASDAI. We recorded sociodemographics s (age, gender) and serological markers.

Results: 75 patients with PSO were referred, 49/45.3% women, mean age 48.9 years. Three patients presented PsA (4%), all peripheral disease (2 oligoarticular and 1 monoarticular) and all of them met the CASPAR criteria. Average ESR 9.42 mmHg, average CRP 1.85 mg/l. Seventeen patients (22.6%) had score pass >47, average 55.4 (47–75). A patient (33.3%) with PsA showed PASE<47. Three patients were diagnosed by a rheumatologist of having PsA (sensitivity 17.6%) from those having PASE >47. DAS28 and ANKYLOSING scores: mean DAS28 2.36 (1.6–3.6), mean ANKYLOSING 2.64 (0.08–10). Of these, 7 patients showed DAS28 >2.6, and 7 patients an ANKYLOSING >4 (41.1%). The 3 patients with diagnosis of PsA had BASDAI >4. 75 patients with PSO were referred, 49/45.3% women, mean age 48.9 years.

Conclusions: The PASE questionnaire, pending of expanding the study with a larger number of included patients, did not show as a useful tool particularly in detecting PsA, showing a lower sensitivity than published. The presence of a high PASE, the realization of measures of activity until there be a diagnostic confirmation of APSO by a rheumatologist is not recommended. CASPAR criteria were met in all patients with PsA. As limitation for our findings we might point out: the low prevalence of PsA shown by patients (may be due to the low number of patients included yet) and the clinical practice setting.

Disclosure of Interest: None to declare.

P099

Skin-homing and systemic T-cell subsets show higher activation in atopic dermatitis versus psoriasis

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Introduction: Atopic dermatitis (AD) and psoriasis are characterized by T-cell infiltration in lesions, but their comparable systemic T-cell activation is unclear.

Objectives: To compare T-cell activation and cytokine polarizations in blood of adult AD and psoriasis patients using flow-cytometry.

Methods: We measured cytokines, Tregs, and T-cell activation markers in central and effector memory (Tcm and Tem) skin homing/cutaneous lymphocyte antigen (CLA^+) and CLA^- subsets from 24 psoriasis patients, 35 AD patients and 13 controls. Early (CD69), mid (ICOS), and late (HLA-DR) activation markers were quantified in Tcm ($CCR7^+CD45RO^+$) and Tem ($CCR7^-CD45RO^+$) populations.

Results: AD showed higher frequency of CLA^+ ''polar'' T-cell subsets ($P<0.0001$). In both diseases, CLA^+ T-cells were significantly more activated compared to respective CLA^- subsets ($P<0.01$), suggesting their prominent role in inflammatory skin diseases. AD demonstrated higher levels of ICOS/HLA-DR activation in circulating CLA^+ and CLA^- memory subsets ($P<0.01$). CD69 was the only activation marker that was higher in psoriasis ($P=0.001$), whereas ICOS expression was significantly higher in AD ($P<0.0001$), compatible with their respective roles in Th17 and Th2 responses. Significant correlations with SCORAD were observed in AD, particularly striking for ICOS ($r=0.5$, $P<0.01$). Higher $CD25^+CD127^-CCR4^+CLA^+$ Tregs were found in AD, correlating with SCORAD and IgE.

Conclusions: Compared with psoriasis, AD is characterized by increased polar differentiation of Tcm/Tem subsets, with higher, persistent activation particularly within skin homing T-cells. Higher systemic activation in AD might reflect the abnormalities seen in non-lesional skin in AD compared to psoriasis, emphasizing the large need for systemic treatment approaches for severe AD patients.

Disclosure of Interest: None to declare.

P101

Scalp psoriasis as a surrogate marker for psoriatic arthritis severity and treatment response

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Objectives: The objective of this analysis was to determine if baseline scalp PsO is associated with baseline severity of PsA and if it is predictive of treatment response to etanercept (ETN).

Methods: Patients with PsA plus PsO from the PRESTA study (clinicaltrials.gov NCT00245960) who received ETN 50 mg once weekly (QW) for 24 wks ($n=373$) were analysed by their scalp PsO status (scalp+ versus scalp–). Baseline characteristics, and improvements at Week 12 and 24 in CRP levels, skin and joint measures, and patient-reported outcomes (PROs) were investigated in scalp+ versus scalp– patients. The % of patients achieving dactylitis ⩽1, enthesitis ⩽1, and HAQ ⩽0.5 at Wks 12 and 24 were also calculated.

Results: In the ETN QW cohort, 273/373 (73.2%) patients had scalp PsO. Spondyloarthropathy was the only PsA subtype shown to be significantly higher in scalp+ versus scalp– patients: 43/49 (87.8%) versus 521/702 (74.2%; $P=0.03$). Scalp– patients were older (49.4 years versus 46.0; $P=0.010$) and more were female (52% versus 33%; $P=0.001$). At baseline, scalp– patients had a significantly higher number of painful joints (28-joint count) but a lower PtGA of PsO than scalp+ patients. Improvements in CRP levels and skin measures were similar in both scalp PsO groups. Scalp+ patients showed significantly greater improvements from baseline at Wks 12 and 24 for both the fatigue and patient assessment of joint pain measures. Improvement in the number of painful joints (28-joint count) was significantly greater for the scalp– group with similar final Wk 12 and 24 results for scalp+ and scalp– patients. Significantly more patients in the scalp– group had dactylitis ⩽1 at Wk 24 and enthesitis ⩽1 at Wk 12, but significantly more scalp+ patients had HAQ ⩽0.5 at Wk 12.

Conclusion: Significant differences were observed in joint involvement and PROs in patients with scalp+ versus scalp– at baseline and after 12 and 24 wks of ETN treatment, indicating a relationship between joint involvement and scalp PsO status and between quality of life and scalp PsO status.

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P102

Ixekizumab in patients with psoriasis and psoriatic arthritis: Pooled analysis of three phase 3 studies in moderate-to-severe psoriasis

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Introduction: Psoriasis (Ps) and psoriatic arthritis (PsA) are chronic inflammatory conditions in which interleukin (IL)-17A plays a central role in the immune pathogenic process. Ixekizumab is an anti-IL-17A monoclonal antibody currently under investigation for treatment of Ps and PsA.

Objective: To examine the effect of ixekizumab on joint pain, quality of life (QoL), and psoriatic skin symptoms in a subset of patients with self-reported PsA from an integrated database of patients with moderate-to-severe Ps.

Methods: In three 12-week, double-blind, phase 3 trials, patients were randomized to receive subcutaneous placebo ($N=792$) or a single injection of 80 mg ixekizumab every 2 weeks (IXE Q2W; $N=1169$) or 4 weeks (IXE Q4W; $N=1165$), following a 160 mg starting dose at Week 0. Of the 3126 enrolled patients, 752 (24.1%) had self-reported PsA. Joint pain was assessed by Joint Pain Visual Analog Scale (VAS; 0 = no pain to 100 = worst pain), QoL by Dermatology Life Quality Index (DLQI) and SF-36 Mental Component Score (MCS) and Physical Component Score (PCS), and skin symptoms by PASI.

Results: Across patients with self-reported PsA, baseline Joint Pain VAS was 49.6, baseline PASI score was 21.6, and baseline DLQI was 14.2. At Week 12, significantly greater improvements in Joint Pain VAS were observed in the IXE Q2W (-26.8 ± 1.5) and IXE Q4W (-25.2 ± 1.5) groups compared to placebo (1.1 ± 1.8; $P<0.001$). Patients receiving IXE Q2W and IXE Q4W achieved significantly greater improvements in DLQI (-11.8 ± 0.3 and -10.5 ± 0.3, respectively) compared to placebo (-0.8 ± 0.4) and had significantly greater improvements in MCS (5.2 ± 0.5 and 4.2 ± 0.5, respectively) and PCS (5.4 ± 0.5 and 5.1 ± 0.5, respectively) compared to placebo (MCS: 0.8 ± 0.6; PCS: -1.1 ± 0.6), ($P<0.001$, for all three measures). PASI 75 was achieved by 89.8% and 81.1% of patients receiving IXE Q2W and IXE Q4W, respectively, compared to 2.9% in patients receiving placebo ($P<0.001$).

Conclusions: In patients with Ps and co-morbid PsA, ixekizumab demonstrated significant improvements in joint pain, QoL, and skin symptoms compared with placebo. These data strongly support the continued evaluation of ixekizumab in patients with PsA.

Disclosure of Interest: A. Gottlieb Grant/Research support from: Centocor (Janssen Biotech), Amgen, Abbott (AbbVie), Novartis AG, Celgene, Pfizer, Eli Lilly and Company, Coronado Biosciences, Daavlin (Levia), Merck & Co, XenoPort, Consultant of: Amgen, Astellas Akros, Centocor (Janssen Biotech), Celgene, Bristol-Myers Squibb, Beiersdorf AG, Abbott (AbbVie), TEVA Pharmaceutical Industries, Actelion Pharmaceuticals, Novo Nordisk, Novartis, Dermipsor, Incyte, Pfizer, Can-Fite BioPharma, Eli Lilly and Company, Coronado Biosciences, Vertex Pharmaceuticals, Karyopharm Therapeutics, CSL Behring, GlaxoSmithKline, XenoPort, Catabasis, Sanofi SA, DUSA Pharmaceuticals; K. Papp Grant/Research support from: Abbott, Amgen, Anacor, Astellas, Celgene, Celtic, Dow Pharma, Eli Lilly and Company, Galderma, Janssen, Janssen Biotech, Merck, Novartis, Pfizer, Consultant of: 3M, Abbott, Akesis, Akros, Alza, Amgen, Astellas, Baxter, Boehringer Ingelheim, Celgene, Centocor, Cipher, Eli Lilly and Company, Forward Pharma, Funxional Therapeutics, Isotechnika, Janssen, Janssen Biotech, Johnson & Johnson, Kataka, Kirin, Kyowa, Lypanosys, Medical Minds, Merck, Mitsubishi Pharma, Novartis, Pfizer, Serono, Takeda, UCB, Vertex, Wyeth, Speakers bureau of: 3M, Abbott, Amgen, Astellas, Janssen, Merck, Novartis, Pfizer; K. Callis Duffin Grant/Research support from: AbbVie, Amgen, Eli Lilly and Company, Pfizer, Bristol-Myers Squibb, Janssen, Celgene, Novartis, XenoPort, Consultant of: AbbVie, Amgen, Eli Lilly and Company, Pfizer, Bristol-Myers Squibb, Janssen, XenoPort, Novartis; C. Birbara Grant/Research support from: Eli Lilly and Company, AbbVie, Merck & Co, Amgen, Genentech, Pfizer, Regeneron Pharmaceuticals, MedImmune; R. Cuchacovich Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company; C. Shuler Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company; R. Burge Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company; J. Erickson Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company; L. Kerr Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company; P. Mease Grant/Research support from: Abbott, Amgen, Biogen Idec, Bristol-Myers Squibb, Celgene, Crescendo, Forest, Genentech, Janssen, Eli Lilly and Company, Merck, Novartis, Pfizer Inc, UCB, Consultant of: Abbott, Amgen, Biogen Idec, Bristol-Myers Squibb, Celgene, Crescendo, Forest, Genentech, Janssen, Eli Lilly and Company, Merck, Novartis, Pfizer Inc, UCB.

P103

Baseline characteristics of patients with moderate to severe plaque psoriasis: post-hoc analysis of response to etanercept

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Introduction: Baseline (BL) characteristics play an important role in patients' (pts) response to treatment.

Objectives: An exploratory post-hoc analysis of pooled data from pts with moderate to severe plaque psoriasis (PsO) in PRISTINE[1] and CRYSTEL[2] to compare the BL characteristics of responders versus non-responders to etanercept (ETN) after 24 wks.

Methods: BL characteristics of pts were analysed for change in Psoriasis Area Severity Index (PASI) and categorised as good ($\geqslant$75%), partial (50%$\leqslant$PASI$<$75%) or failed (PASI$<$50%) response at Wk 24.

Results: Pts who achieved a good PASI response had lower mean body weight (82.8 kg) versus partial or failed responders (87.1 kg and 86.0 kg, respectively). BL PASI was higher in pts who achieved a good PASI response (23.3) versus partial or failed responders (22.1 and 19.3, respectively) (Table). Pts who were good PASI responders were less likely to be on disease-modifying antirheumatic drugs at BL (26.7%) versus partial or failed responders (43.7% and 50.8%, respectively). This trend was also noted in pts on topical steroids at BL (Table).

Conclusion: Several baseline characteristics were statistically different between pts with good, partial and failed PASI responses to ETN at Wk 24.

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[P103] Table 1

BL characteristic	Good response ($\geqslant$75%) ($n=490$)	Partial response (50%$\leqslant$PASI$<$75%) ($n=245$)	Failed response (PASI$<$50%) ($n=246$)
Weight, kg	82.8 (18.8)	87.1 (17.1)	86.0 (19.6)**
BSA, m^2	2.0 (0.3)	2.1 (0.2)	2.0 (0.3)**
PhysGA	3.6 (0.7)	3.6 (0.7)	3.5 (0.7)*
PASI	23.3 (10.1)	22.1 (10.7)	19.3 (8.8)***
Any DMARDs excluding MTX, n (%)	131 (26.7)	107 (43.7)	125 (50.8)***
Topical steroids, n (%)	138 (29.0)	85 (35.3)	95 (38.9)*
Prior systemic therapy, n (%)[a]	336 (70.6)	200 (83.0)	216 (88.5)***
PhysGA of BSA	14.6 (18.2)	9.3 (14.7)	8.4 (15.2)***

PhysGA, physician's global assessment.
Data are mean (SD) or n (%); LOCF.
*$P<0.05$; **$P<0.01$; ***$P<0.001$ (Statistically significant across 3 response categories);[a]Screening to BL.

P104

Asymptomatic psoriatic arthritis: An ultrasonography study

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Objective: Psoriasis is a chronic inflammatory disease of skin and joints. In our study we aimed to investigate joint and enthesis regions of psoriasis patients without inflammatory joint symptoms by ultrasonography (US) to detect subclinical PsA and to determine if there are associations between detected findings and signs of skin and nail psoriasis.

Methods: Fifty psoriasis and 30 healthy control subjects without joint complaint are included in the study. Patients with history of trauma, medications or illnesses that may affect joints were excluded. Disease type, duration, PASI value and nail findings of psoriasis patients were recorded. Bilateral shoulders, elbows, flexor and extensor tendons of hands, knees, Achilles tendons and plantar fascias of each of the two groups were examined by US.

Results: Psoriatic patients' pathological US findings (30%) were higher than control group's (13.3%). However, this elevation was not statistically significant. The age, gender, psoriasis duration, PASI and nail involvement of psoriasis patients with pathological US findings were not different from the group without pathological US findings. The most common pathological findings were observed on the knee joint in psoriasis patients. In the psoriasis group millimetric calcifications on enthesis region (22%), bone surface irregularity (8%) and enthesal thickening (2%) were observed. In the control group the only manifestation was millimetric calcifications on enthesis (%13,3). Although millimetric calcification rate was significantly higher in the psoriasis group, the rate was not statistically significant between the control and psoriasis groups.

Conclusion: In our study various joints were investigated with US. There are very few publications in the literature, contrary to our study few joints are investigated in these publications. Our results are not statistically significant but pathologic US findings in psoriatic patients were more than twice higher than control group. Therefore we believe that psoriatic patients without joint complaints should also be monitored for psoriatic arthritis development.

Disclosure of Interest: None to declare.

P105

A clinical survey of nail findings of psoriasis and review of the literature

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Background: There are still scarce data about the incidence rates of detailed findings of nail psoriasis.

Objective: Herein this study, it was intended to investigate the frequency of the different types of nail involvement in psoriasis, and review the data of nail involvement.

Methods: 176 consecutive patients with psoriasis were included to the study. Each nail finding of groups constituted according to the involvement or non-involvement of nails with psoriasis, was assessed for pitting, onycholysis, discoloration, hyperkeratosis, oil spot and other nail changes. The same assessments were made for fingernail and toenail involvement, and for great toenail and other toenail involvements. The nail findings of each group were compared with each other according to age, gender of patients, duration and family history of psoriasis, PASI scores.

Results: There were 85 patients with psoriatic nail involvement and 91 patients with non-involvement. The nail involvement was more frequent in male psoriatic patients and in the patients who had a relative with psoriasis. The median duration of psoriasis was longer and PASI scores were higher in nail involved patients. The fingernails proved to be affected much frequently than toenails as found in our study. The incidence rates were pitting, discoloration of the nail plate, distal onycholysis, subungual hyperkeratosis, other findings and oil spot respectively. The fingernails were more frequently involved in psoriasis than the toe nails.

Conclusion: Contrary to other publications nail involvement is more observed in male psoriasis cases, in cases which have psoriasis in family, in cases which have psoriasis for a long period of time and in cases which have a high PASI value in our study.

Disclosure of Interest: None to declare.

P106

Bone density and metabolism with disease condition in psoriatic arthritis after treatment with adalimumab for 52 weeks

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Introduction: Adalimumab (ADA) has shown significant efficacy in the treatment of arthritis, spondylitis, and skin lesions in psoriatic arthritis (PsA) patients. Although therapeutic benefits have been published, little information has been reported regarding bone mineral density (BMD) and metabolism during treatment.

Objectives: We investigated whether ADA treatment modifies BMD and metabolism in PsA patients in clinical practice.

Methods: From March 2010 to December 2012, twenty-three patients were eligible for the study (male 19, female 4), and the average age and affected period (psoriasis/PsA) were 46.5 ± 9.6 years old and 16.2 ± 10.1/5.7 ± 6.0years, respectively. Patients were segmented into Spondylitis (SP) group (18/23) according Moll and Wright Criteria were extracted and compared with the others (peripheral (PE) group: 5/23). BMD (%YAM) of lumbar vertebrae (LV) and left side of the femoral neck(FN)/total proximal femur(PF) on DXA were measured at baseline and 52 weeks after treatment.TRACP-5b, BAP, serum Calcium, ucOC were measured at baseline and 24, 52 weeks after treatment. Wilcoxon signed rank test was used and significance level was set at 0.05.

Results: In this study, there were two osteoporosis and two osteopenia.

The mean %YAM in LV increased significantly from 95.1 ± 9.6 % to 96.7 ± 10.0% ($P = 0.0238$). The SP group increased significantly from 93.8 ± 10.3 % to 95.8 ± 11.2 % ($P = 0.0181$) in the mean value of %YAM in LV.

The SP group increased significantly from 90.9 ± 11.6 % to 92.7 ± 11.7% ($P = 0.0173$) in the mean value of %YAM in FN. In the mean value of %YAM in PF, the SP group increased significantly from 96.8 ± 11.4% to 97.9 ± 10.9 % ($P = 0.0457$).The mean ucOC increased significantly from 3.3 ± 2.0/ 3.43 ± 2.21 at baseline to 4.6 ± 2.8/4.90 ± 3.01 at week 52 ($P = 0.0333/0.0364$) in all patients and the SP group.The mean TRACP-5b of the SP group decreased from 302.2 ± 61.7 at baseline to 246.8 ± 95.3 at week 52.

Conclusions: BMD in lumbar vertebrae, left side of the femoral neck and total proximal femur in the spondylitis (SP) group of PsA patients significantly increased during ADA treatment.

Disclosure of Interest: None to declare.

P107

Psoriasis and psoriatic arthritis relationship

Işıl Deniz Oğuz[1], Ülker Gül[2], Salih Süha Koparal[3], Tağmaç Deren[3], Seray Külcü Çakmak[1], Hatice Bodur[4], Özlem Yılmaz[4]

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Objective: Psoriasis is a chronic inflammatory disease of skin and joints. In our study we aimed to investigate joint and enthesis regions of psoriasis patients without inflammatory joint symptoms by ultrasonography (US) to detect subclinical PsA and to determine if there are associations between detected findings and signs of skin and nail psoriasis.

Material and methods: Fifty psoriasis and 30 healthy control subjects without joint complaint are included in the study. Patients with history of trauma, medications or illnesses that may affect joints were excluded. Disease type, duration, PASI value and nail findings of psoriasis patients were recorded. Bilateral shoulders, elbows, flexor and extensor tendons of hands, knees, Achilles tendons and plantar fascias of each of the two groups were examined by US.

Results: Psoriatic patients' pathological US findings (30%) were higher than control group's (13.3%). However, this elevation was not statistically significant. The age, gender, psoriasis duration, PASI and nail involvement of psoriasis patients with pathological US findings were not different from the group without pathological US findings. The most common pathological findings were observed on the knee joint in psoriasis patients. In the psoriasis group millimetric calcifications on enthesis region (22%), bone surface irregularity (8%) and enthesal thickening (2%) were observed. In the control group the only manifestation was millimetric calcifications on enthesis (%13,3). Although millimetric calcification rate was significantly higher in the psoriasis group, the rate was not statistically significant between the control and psoriasis groups.

Conclusion: In our study various joints were investigated with US. There are very few publications in the literature, contrary to our study few joints are investigated in these publications. Our results are not statistically significant but pathologic US findings in psoriatic patients were more than twice higher than control group. Therefore we believe that psoriatic patients without joint complaints should also be monitored for psoriatic arthritis development.

Disclosure of Interest: None to declare.

P108

Prevalence of psoriatic arthritis among patients with psoriasis in Greece: A large observational study

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Introduction: The exact prevalence of psoriatic arthritis (PsA) among psoriasis patients is still not conclusive. Literature data vary between 5.9–23.9% with limited data in South & Eastern Europe and no data in Greece.[1,2]

Objectives: Our study's aim was to evaluate PsA prevalence & characteristics in psoriasis patients examined in a specialized clinic of a University Hospital.

Methods: An observational study was conducted in Attikon Hospital, Greece. Between 09–02/ 2013, 278 consecutive psoriasis patients were evaluated by a rheumatologist for PsA using Wright & Moll's criteria. Laboratory & radiological tests were performed. Demographic & clinical data were collected.

Results: The study included 278 patients, median age 51.41, median psoriasis presenting age 34.52. Referring to psoriasis type 86% presented with plaque, 5% guttate, 2% palms and soles, 2% inverse, 1% pustular and 4% of more than one type. Nail disease appeared in 121 and scalp disease in 175. Among them 31% had PsA whereas 51% of PsA patients had nail disease. Referring to PsA type, 51% patients had polyarthritis, 12% oligoarthritis, 8% axial arthritis. The rest 31% had PsA of more than one type or did not fulfill the tests. Comorbidities were more frequent in PsA compared to non PsA patients; hypertension presented in 41% versus 17% ($P = 0.001$), diabetes in 20% versus 8% ($P = 0.021$) and hypercholesterolemia in 41% versus 19% ($P = 0.004$), respectively.

Conclusion: PsA prevalence among psoriasis patients was relatively high compared with other ethnic based studies. Comorbidities relating with life expectancy appear to be higher. We believe that there is a high percentage of undiagnosed cases with active arthritis among psoriasis patients and dermatologists should be aware of PsA clinical signs in order to promote earlier recognition and successful treatment.

Disclosure of Interest: None to declare.

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P110

Screening of psoriatic arthritis in Korean psoriasis patients using PASE

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Introduction: Early recognition of PsA in patients with psoriasis is important for preventing physical disability and deformity.

Objective: The aim of this study was to validate the Psoriatic Arthritis Screening Evaluation (PASE) questionnaire for the detection of PsA in Korean patients with psoriasis.

Methods: The PASE questionnaire was prospectively administered to 148 patients with a diagnosis of psoriasis. All patients underwent radiologic and laboratory examinations, and a subsequent clinical evaluation by a rheumatologist.

Results: Eighteen psoriasis patients (12.7%) were diagnosed as having PsA meeting the Classification Criteria for Psoriatic Arthritis (CASPAR). PASE questionnaire scores of patients with PsA were significantly different from the scores of those without PsA. Receiver operator curves showed an area under the curve of 0.82 (95% CI 0.72, 0.92) for PASE score. A PASE score cut-off value of 37 points had a sensitivity of 77.8% and specificity of 82.3% for the diagnosis of PsA.

Conclusions: The PASE questionnaire is a simple and convenient screening tool for detecting PsA in Korean dermatologic clinics.

Disclosure of Interest: None to declare.

P111

Similarities in coronary function and myocardial deformation between psoriasis and coronary artery disease: The role of oxidative stress and inflammation

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Introduction: Psoriasis has been associated with increased risk for coronary artery disease (CAD). We investigated the presence of vascular and subclinical left ventricular (LV) dysfunction in patients with psoriasis compared with patients with CAD.

Methods: We compared 59 patients with psoriasis without evidence of CAD (psoriasis area and severity index [PASI], 11.5 ± 8) with 59 patients with angiographically documented CAD and 40 controls. We measured (1) the carotid-femoral pulse wave velocity (PWVc) and central augmentation index (CAI), (2) coronary flow reserve (CFR) by Doppler echocardiography, (3) flow-mediated dilation (FMD) of the brachial artery and carotid intima media thickness (IMT), (4) LV global longitudinal strain (GLS) and GLS rate (GLSR) using speckle tracking echocardiography, and (5) malondialdehyde (MDA) and interleukin-6 (IL-6) levels.

Results: Patients with psoriasis had higher PWVc, CAI, IMT, MDA, and IL-6 levels and lower FMD, CFR, GLS, and GLSR than did controls ($P<0.05$), but they had values of these markers that were similar to those of patients with CAD ($P>0.05$) after adjustment for atherosclerotic risk factors: (PWVc [m/s], 10.4 ± 1.8 versus 8.6 ± 1.5 versus 10.3 ± 2, respectively; CAI (%), 27 ± 17 versus 17 ± 11 versus 31 ± 15 respectively, IMT (mm), 0.8 ± 0.2 versus 0.66 ± 0.2 versus 0.87 ± 0.2, respectively, CFR, 2.4 ± 0.1 versus 3.4 ± 0.6 versus 2.6 ± 0.6, respectively;FMD(%),6 ± 4versus9 ± 2versus5,1 ± 2respectively, GLS [%], −16.2 ± 4 versus −21.9 ± 1.6 versus −16.6 ± 4.5, respectively; GLSR [L/sec], −0.85 ± 0.2 versus −1.2 ± 0.12 versus −0.9 ± 0.4, respectively; MDA [nM/l], 1.68 versus 1.01 versus 1.76, respectively; IL-6 [pg/ml], 2.26 versus 1.7 versus 2.2, respectively; $P<0.05$ for all comparisons). PASI was related to IMT ($r=0.67$; $P<0.01$). Decreased GLS was associated with increased MDA, IL-6, PWVc, CAI, and reduced CFR ($P<0.05$).

Conclusions: Psoriasis and CAD present similar vascular and LV myocardial dysfunction, possibly because of similar underlying inflammatory and oxidative stress processes. Vascular dysfunction in psoriasis is linked to abnormal LV myocardial deformation.

Disclosure of Interest: None to declare.

P112

Screening for PsA in primary care psoriasis patients with musculoskeletal complaints with PEST, PASE & EARP

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Background: Several screening tools have been developed to enhance early recognition of psoriatic arthritis (PsA). However, most were developed in secondary care, while early recognition should ideally take place in primary care.

Objective: To evaluate the screening performance of the PEST, PASE and EARP to identify psoriatic arthritis among primary care psoriasis patients with recurrent spells of musculoskeletal complaints (MSC).

Methods: A cross-sectional study was set up. Adult primary care patients were selected by ICPC code S91 for psoriasis, the presence of recurrent spells of MSC (joints, enthesis or low back pain) was determined by telephone interview. Patients completed the PEST, PASE & EARP questionnaires before clinical evaluation by a trained research nurse. When patients reported a painful enthesis on LEI/MASES, an ultrasound of the entheses was performed. A PsA case fulfilled the CASPAR criteria. Sensitivity and specificity were determined for the PEST and EARP cut off ⩾3 and PASE cut off ⩾44 as well as ⩾47.

Results: 473 psoriasis patients participated with a mean ± SD age of 55.7 ± 13.9 years and 50.9% being male. Median PASI score was 2.3 (IQR 1–4) and 71 patients (15.0%) had nail abnormalities related to psoriasis. We found 17 new cases of PsA (3.6%) as diagnosed by a rheumatologist. Moreover, we found 36 cases of enthesitis, confirmed by ultrasound. The majority of these refrained from further evaluation by a rheumatologist, however most of them would classify as PsA according to the CASPAR criteria. Looking into all cases, including enthesitis, the EARP had a sensitivity of 87% and a specificity of 33%, for the PEST this was 68% and 71%. The PASE had a sensitivity of 66% and a specificity of 55% at the cut off of ⩾44 and 59% and 64% at the cut off of⩾47. Similar figures were observed if only axial manifestations and arthritis were taken into account.

Conclusion: Modest sensitivity was observed for the PEST and PASE with an acceptable specificity for the PEST, while the EARP had high sensitivity and low specificity, which is undesirable for screening. The performance of all screening tools was lower than previously reported in secondary care settings.

Disclosure of Interest: None to declare.

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Secukinumab improves active psoriatic arthritis and inhibits radiographic progression: Results of a phase 3 randomized, multicenter, double-blind, placebo-controlled study

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Introduction: Significant efficacy has been demonstrated with secukinumab in psoriasis.

Objective: To report the efficacy and safety of secukinumab in patients (pts) with psoriatic arthritis (PsA) (FUTURE 1; NCT01392326).[1]

Methods: 606 pts were randomized to placebo (PBO) or secukinumab 10 mg/kg i.v. at baseline (BL), Weeks (Wks) 2 and 4, then 150 mg s.c. (10 IV→150 SC) or 75 mg s.c. (10 IV→75 SC) every 4 wks from Wk 8. At Wk 16 or 24, PBO pts were switched to secukinumab based on response. The primary endpoint was ACR20 response at Wk 24. Secondary endpoints included PASI 75/90, DAS28-CRP, SF-36 PCS, HAQ-DI, ACR50, mTSS, dactylitis and enthesitis.

Results: Baseline characteristics were balanced between groups. Secukinumab significantly improved ACR20 responses versus PBO at Wk 24 (Table). All pre-specified secondary endpoints were also significantly improved at Wk 24 and improvements sustained through Wk 52. At Wk 52, observed ACR20/50 responses were 69.5%/50.0% for 10 IV→150 SC and 66.9%/38.4% for 10 IV→75 SC. During safety reporting period (mean secukinumab exposure 438.5 days; mean placebo exposure 128.5 days), exposure-adjusted incidence rates of AEs/serious AEs were 229.0/11.5, 183.2/7.4, and 324.9/16.0 cases/100 pt-years for secukinumab 150 mg, 75 mg and PBO, respectively.

Conclusions: Secukinumab provided rapid, significant and sustained improvements in signs and symptoms of PsA and inhibited radiographic disease progression. Secukinumab was well tolerated through Wk 52.

Disclosure of Interest: P. Mease Grant/Research support from: AbbVie, Amgen, Biogen Idec, BMS, Celgene, Crescendo, Janssen, Lilly, Merck, Novartis, Pfizer, UCB, and Vertex, Consultant of: AbbVie, Amgen, Biogen Idec, BMS, Celgene, Covagen, Crescendo, Janssen, Lilly, Merck, Novartis, Pfizer, UCB, and Vertex, Speakers bureau of: AbbVie, Amgen, Biogen Idec, BMS, Crescendo, Janssen, Lilly, Pfizer, and UCB; I. B. McInnes Consultant of: Novartis, Amgen, Janssen, BMS, Pfizer, UCB, Abbvie, Celgene and Lilly; B. Kirkham Grant/Research support from: AbbVie and UCB, Consultant of: Novartis, AbbVie, BMS, Lilly, and MSD, Speakers bureau of: BMS, MSD, and UCB; A. Kavanaugh Consultant of: Novartis; P. Rahman Consultant of: Abbott, AbbVie, Amgen, BMS, Celgene, Janssen, Novartis, Pfizer and Roche; D. V. D. Heijde Grant/Research support from: AbbVie, Amgen, AstraZeneca, Augurex, BMS, Celgene, Centocor, Chugai, Covagen, Daiichi, Eli-Lilly, Galapagos, GSK, Janssen Biologics, Merck, Novartis, Novo-Nordisk, Otsuka, Pfizer, Roche, Sanofi-Aventis, Schering-Plough, UCB, Vertex, Consultant of: AbbVie, Amgen, AstraZeneca, Augurex, BMS, Celgene, Centocor, Chugai, Covagen, Daiichi, Eli-Lilly, Galapagos, GSK, Janssen Biologics, Merck, Novartis, Novo-Nordisk, Otsuka, Pfizer, Roche, Sanofi-Aventis, Schering-Plough, UCB, Vertex, Employee of: Imaging Rheumatology bv; R. Landewé Grant/Research support from: Abbott, Amgen, Centocor, Novartis, Pfizer, Roche, Schering-Plough, UCB, Wyeth, Consultant of: Abbott/AbbVie, Ablynx, Amgen, Astra-Zeneca, Bristol-Myers Squibb, Centocor, GlaxoSmithKline, Novartis, Merck, Pfizer, Roche, Schering-Plough, UCB, Wyeth, Employee of: Rheumatology Consultancy BV, Speakers bureau of: Abbott, Amgen, Bristol-Myers Squibb, Centocor, Merck, Pfizer, Roche, Schering-Plough, UCB, Wyeth; P. Nash Grant/Research support from: Novartis, Abbvie, Roche, Pfizer, BMS, Janssen, and Celgene, Speakers bureau of: Novartis, Abbvie, Roche, Pfizer, BMS, Janssen, and Celgene; L. Pricop Shareholder of: Novartis , Employee of: Novartis; J. Yuan Employee of: Novartis; H. Richards Employee of: Novartis; S. Mpofu Shareholder of: Novartis, Employee of: Novartis.

References: 1. Mease P *et al. Arthritis Rheumatol.* 2014;66:S423–4.

[P113] Table 1. Selected 24-wk results

	Secukinumab 10 mg/kg IV→ 150 mg SC $n=202$	Secukinumab 10 mg/kg IV→ 75 mg SC $n=202$	PBO $n=202$
ACR20/50 (% responders)	50.0*/34.7*	50.5*/30.7*	17.3/7.4
PASI75/90 (% responders)[a]	61.1*/45.4*	64.8*/49.1*	8.3/3.7
DAS28-CRP (mean change from BL)	–1.62*	–1.67*	–0.77
SF-36 PCS (mean change from BL)	5.41*	5.91*	1.82
HAQ-DI (mean change from BL)	–0.41*	–0.40*	–0.17
mTSS	0.13‡	0.02‡	0.57
[a]Dactylitis (resolution of, %) Overall ($n=324$)	48.1*	56.7*	15.5
[a]Enthesitis (resolution of, %) Overall ($n=372$)	46.0*	48.8*	12.8

*$P<0.0001$,‡$P<0.05$ versus PBO.
[a]Pts with ⩾3% of body surface area with psoriasis; $n=108$, 108, and 109, respectively.

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Secukinumab improves signs and symptoms of active psoriatic arthritis: Results from a phase 3 randomized, multicenter, double-blind, placebo-controlled study using a subcutaneous dosing regimen (FUTURE 2)

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Introduction: Secukinumab, a human anti–IL-17A monoclonal antibody, has shown efficacy with an i.v. loading and s.c. maintenance regimen in psoriatic arthritis (PsA) (FUTURE 1).

Objective: To evaluate the efficacy and safety of secukinumab s.c. loading and maintenance dosing in FUTURE 2 (NCT01752634) in patients (pts) with active PsA.[1]

Methods: 397 adults with active PsA were randomized to s.c. secukinumab (300, 150 or 75 mg) or placebo (PBO) at baseline, Week (Wk) 1, 2, 3, 4 and then every 4 wks thereafter. The primary endpoint was ACR20 response at Wk 24. Secondary endpoints included PASI 75/90, Disease Activity Score 28 using C-reactive protein (DAS28-CRP), Short Form-36 Physical Component Summary (SF-36 PCS), Health Assessment Questionnaire-Disability Index (HAQ-DI), ACR50, dactylitis and enthesitis.

Results: At Wk 24, ACR20 responses were significantly greater with secukinumab 300, 150 and 75 mg versus PBO: 54.0%, 51.0% and 29.3% versus 15.3%, respectively ($P<0.0001$ for secukinumab 300 and 150 mg; $P<0.05$ for 75 mg versus PBO). Secukinumab 300 and 150 mg also significantly improved PASI 75/90 scores and DAS-28 CRP versus PBO (Table). Exposure-adjusted rates of AEs and SAEs were 222.2/309.3 per 100 pt-years and 7.8/8.8 amongst secukinumab- (pooled) and PBO-treated subjects, respectively.

Conclusions: Secukinumab 300 and 150 mg s.c. demonstrated clinically significant improvements in the signs and symptoms of active PsA. Secukinumab was well tolerated through 24 weeks.

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References:
1. McInnes IB, *et al.* at the ACR/ARHP Annual Meeting, Boston, MA, USA. November 14–19, 2014. Oral Presentation L1.

[P114] Table 1. Summary of Selected 24-Week Efficacy Results

	Secukinumab 300 mg s.c.	Secukinumab 150 mg s.c.	Secukinumab 75 mg s.c.	PBO
ACR20/50 (% responders)	54.0*/35.0§	51.0*/35.0	29.3‡/18.2	15.3/7.1
PASI 75/90 (% responders)	63.4*/48.8†	48.3§/32.8§	28.0/12.0	16.3 /9.3
DAS28-CRP, (mean change from baseline)	–1.61§	–1.58§	–1.12	–0.96
[a]Dactylitis (% resolution)	56.5	50.0	30.3	14.8
[a]Enthesitis (% resolution)	48.2	42.2	32.4	22.5

*$P<0.0001$;†$P<0.001$;§$P<0.01$;‡$P<0.05$ versus PBO; *P*-values adjusted for multiplicity.
[a]Data from patients with dactylitis ($n=138$) and enthesitis ($n=253$) at baseline.

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Secukinumab is effective in reducing dactylitis and enthesitis using multiple measures in patients with psoriatic arthritis: Results of a phase 3 randomized, multicenter, double-blind, placebo-controlled study (FUTURE 2)

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Introduction: Dactylitis and enthesitis are common disabling manifestations of psoriatic arthritis (PsA).

Objective: To evaluate the effects of subcutaneous (s.c.) secukinumab on dactylitis and enthesitis in the FUTURE 2 study (NCT01752634).[1]

Methods: A total of 397 pts with active PsA were randomized to secukinumab (300, 150 or 75 mg) or placebo (PBO) at baseline (BL), Week (Wk) 1, 2, 3, 4 and then every 4 wks thereafter. The primary endpoint was ACR20 response at Wk 24. The proportions of pts with resolution of dactylitis and enthesitis at Wk 24 were secondary endpoints. Dactylitis counts, Leeds Dactylitis Index (LDI), and Leeds Enthesitis Index (LEI) were also assessed.

Results: At BL, 138 pts (35%) had dactylitis and 253 (64%) had enthesitis. At Wk 24, 56.5%, 50.0%, and 30.3% versus 14.8% of pts had complete resolution of dactylitis, and 48.2%, 42.2% and 32.4% versus 21.5% had complete resolution of enthesitis with secukinumab 300 mg, 150 mg and 75 mg versus PBO, respectively. Corresponding reductions in LDI, LEI and mean dactylitis counts were observed (Table).

Conclusions: Secukinumab 300 and 150 mg s.c. reduced the number of dactylitic digits and enthesitis sites in pts with PsA and was associated with a greater proportion of pts achieving complete resolution of dactylitis and enthesitis versus PBO.

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References:

1. McInnes IB *et al.*: ACR/ARHP Annual Meeting, Boston, MA, USA. November 14–19, 2014. Oral presentation L1.

[P115] Table 1. Dactylitis and enthesitis data

	Secukinumab 300 mg ($n=100$)	Secukinumab 150 mg ($n=100$)	Secukinumab 75 mg ($n=99$)	PBO ($n=98$)
Resolution of Dactylitis at Wk 24, n/N (%)	26/46 (56.5)[§]	16/32 (50.0)[§]	10/33 (30.3)	4/27 (14.8)
LDI at BL, mean (SD)	25.7 (86.5)	12.0 (56.5)	12.7 (39.6)	10.5 (29.3)
LDI at Wk 24 (LS mean change from BL)	–15.13	–11.70	–7.72	–10.19
Dactylitis count at BL, mean (SD)	3.6 (3.5)	4.5 (5.1)	3.0 (3.6)	2.7 (2.2)
Dactylitis count at Wk 24 (LS mean change from BL)	– 2.3	–3.1	–1.0	–0.6
Resolution of Enthesitis at Wk 24, n/N (%)	27/56 (48.2)[§]	27/64 (42.2)[‡]	22/68 (32.4)	14/65 (21.5)
LEI at BL, mean (SD)	1.6 (1.9)	2.0 (2.0)	2.2 (2.0)	2.0 (2.0)
LEI at Wk 16 (mean change from BL)	–0.8	–1.0	–0.8	–0.4

[§]$P<0.01$;[‡]$P<0.05$ for comparisons versus PBO.

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Secukinumab improves physical function, quality of life, fatigue and work productivity in patients with active psoriatic arthritis: Results of a randomized, double-blind, placebo-controlled phase 3 trial (FUTURE 2)

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Introduction: Secukinumab improved the signs and symptoms of psoriatic arthritis (PsA) in the FUTURE 2 study (NCT01752634).[1]

Objectives: To investigate the effect of secukinumab through Week (Wk) 24 on patient-reported outcomes (PROs).

Methods: 397 pts with active PsA were randomized to subcutaneous secukinumab (300, 150 or 75 mg) or placebo (PBO) at baseline (BL), Wks 1, 2, 3 and 4, and every 4 wks thereafter. At Wk 16, PBO non-responders were switched to secukinumab 300 or 150 mg (1:1). PROs were assessed using: Short Form-36 (SF-36) Physical Component Summary (PCS) and Mental Component Summary (MCS); Health Assessment Questionnaire-Disability Index (HAQ-DI); Psoriatic Arthritis Quality of Life (PsAQoL); Functional Assessment of Chronic Illness Therapy—Fatigue (FACIT-F); Work Productivity and Activity Impairment Questionnaire (WPAI-GH) and Dermatology Life Quality Index (DLQI). SF-36 PCS and HAQ-DI were secondary endpoints and other PROs were exploratory endpoints.

Results: At BL, subjects had moderate-to-severe physical impairment and fatigue levels, and impaired HRQoL. At Wk 24, secukinumab 300 and 150 mg improved SF-36 PCS, HAQ-DI (300 mg only), FACIT-F, PsAQoL, DLQI scores (Table), and aspects of work productivity assessed by WPAI-GH versus PBO.

Conclusion: In pts with active PsA, secukinumab 300 and 150 mg improved various patient reported outcomes including physical function, fatigue, HRQoL by generic and disease-specific measures, and reduced the impact of disease on work productivity.

Disclosure of Interest: A. B. Gottlieb Grant/Research support from: Centocor (Janssen), Amgen, Abbott (Abbvie), Novartis, Celgene, Pfizer, Lilly, Coronado, Levia, Merck, Xenoport, Consultant of: Amgen Inc., Astellas, Akros, Centocor (Janssen), Inc. Celgene Corp., Bristol Myers Squibb Co., Beiersdorf, Inc., Abbott Labs. (Abbvie), DUSA, TEVA, Actelion, UCB, Novo Nordisk, Novartis, Dermipsor Ltd., Incyte, Pfizer, Canfite, Lilly, Coronado, Vertex, Karyopharm, CSL Behring Biotherapies for Life, Glaxo SmithKline, Xenoport, Catabasis, Sanofi Aventis; V. Strand Consultant of: AbbVie, Afferent, Amgen, Biogen Idec, Bioventus, BMS, Carbylan, Celgene, Celltrion, CORRONA, Crescendo, Genentech/Roche, GSK, Hospira, Iroko, Janssen, Lilly, Merck, Novartis, Pfizer, Regeneron, Sanofi, SKK, Takeda, UCB, Vertex; I. B. McInnes Consultant of: Novartis, Amgen, Janssen, BMS, Pfizer, UCB, Abbvie, Celgene and Lilly; H. Marzo-Ortega Consultant of: Abbvie, Celgene, Janssen, MSD, Pfizer and UCB; A. Kavanaugh Consultant of: Novartis; S. Kandala Employee of: Novartis; L. Pricop Shareholder of: Novartis, Employee of: Novartis; S. Mpofu Shareholder of: Novartis, Employee of: Novartis.

References:

1. McInnes IB *et al.* Oral presentation L1: ACR/ARHP Annual Meeting, Boston, MA, USA. November 14–19, 2014.

[P116] Table 1. LS mean change from BL to Week 24

PROs	Secukinumab 300 mg $n=100$		Secukinumab 150 mg $n=100$		Secukinumab 75 mg $n=99$		PBO $n=98$	
	BL	Change at Wk 24	BL	Change at Wk 24	BL	Change at Wk 24	BL	Change at Wk 24
SF-36 PCS	36.94	7.25[§]	36.15	6.39[§]	36.23	4.38	37.44	1.95
HAQ-DI	1.28	–0.56[§]	1.22	–0.48	1.16	–0.32	1.17	–0.31
SF-36 MCS	43.64	3.94	40.62	6.07	43.90	4.97	44.05	3.69
FACIT-F	28.60	5.97[§]	26.64	7.97*	28.69	6.20[§]	29.21	1.63
PsAQoL	10.19	–4.23[‡]	11.67	–4.51[‡]	10.29	–3.20	9.83	–1.99
DLQI	12.3	–8.48*	14.4	–8.77*	10.4	–7.43[†]	12.3	–2.13

*$P<0.0001$; [†]$P<0.001$; [§]$P<0.01$, [‡]$P<0.05$ versus PBO; BL, baseline; LS, least square.

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Therapeutic response in adalimumab-treated patients with psoriatic arthritis in relation to weight

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Introduction: It is unknown if elevated CRP is predictive of clinical response to adalimumab (ADA); however, obesity is related to inflammation (measured by CRP) and psoriatic arthritis (PsA) patients (pts) tend to be obese.

Objective: To evaluate effect of weight (wt) on response in ADA treated PsA pts.

Methods: *Post hoc* data analysis from Adept, a 24-wk DB, randomized, PBO-controlled trial in PsA pts. Wt was categorized by quartiles (Q). For each wt and CRP category, Wk12 endpoints were analyzed: Clinical Disease Activity Index (CDAI), Psoriatic Arthritis Response Criteria (PsARC), PASI75, and HAQ. Multivariate (MV) analysis was done accounting for wt and CRP in the model.

Results: 309/313 pts enrolled had data available. Mean wt was 85.8 kg. CRP was elevated in 78.3%. Wt was weakly correlated with CRP at baseline (BL) using non-parametric testing (Kendall Tau-b r = 0.131, $P = 0.006$). Mean wt was higher in elevated v normal CRP group (87.6 kg v 79.4 kg, $P = 0.0012$). BL disease activity (tender/swollen joint count, physician and pt global assessment of disease activity, CDAI, PASI, HAQ) was slightly higher in elevated CRP group. For all outcome measures treatment effect was in favor of ADA; no significant difference was observed across wt Q. In pts with both normal ($n = 67$) and elevated ($n = 242$) CRP statistically significant response in favor of ADA was observed for PASI75, with numerically superior but stastistically nonsignficant results for CDAI, PsARC, and HAQ in pts with nCRP. Wt Q and CRP were not significant in MV model. For CDAI, PsARC and HAQ treatment was statistically significant in favor of ADA regardless of wt/CRP. Sample sizes were too small to make meaningful conclusions for PASI.

Conclusions: The majority of PsA pts in ADEPT had elevated CRP indicating inflammation. Overall, ADA-treated pts had superior response rates compared to PBO-treated pts regardless of wt/CRP category. Limitations include using weight in place of BMI; pt height was not available.

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[P117] Table 1

Table. Wt and CRP categories	Q1	Q2	Q3	Q4
Wt range (kg)	45.4–73.0	73.0–84.4	85.0–96.2	97.0–156.0
Elevated CRP (%)*	67.5	75.3	85.2	84.6
Mean Wt for pts with elevated CRP (kg)	64.6	78.7	90.7	109.7

*$P = 0.021$.

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Apremilast, an oral phosphodiesterase 4 inhibitor, in patients with nail, scalp and palmoplantar psoriasis: 52-Week results from the ESTEEM 2 study

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Introduction: Nail, scalp and palmoplantar psoriasis are difficult to treat.[1]

Objectives: Evaluate the efficacy and safety of apremilast (APR), an oral phosphodiesterase 4 inhibitor, for treatment of nail, scalp and palmoplantar psoriasis over 52wks.

Methods: Pts with moderate to severe plaque psoriasis (PASI ⩾12, BSA ⩾10%, sPGA ⩾3) were randomized 2:1 to APR 30 mg BID (APR) or placebo (PBO). At Wk16, PBO pts switched to APR (PBO/APR). At Wk32, APR pts achieving ⩾PASI-50 response were re-randomized (1:1, blinded) to continue APR or receive PBO. Upon loss of 50% of PASI improvement obtained at Wk32, pts re-randomized to PBO resumed APR. Nail, scalp and palmoplantar psoriasis were assessed by NAPSI, ScPGA and PPPGA.

Results: The full analysis set included 411 pts (PBO $n = 137$; APR $n = 274$). At Wk16, improvements in nail, scalp and palmoplantar psoriasis were significantly greater with APR versus PBO (Table). At Wk32, mean percent change in NAPSI and NAPSI-50 response rates, respectively, were −60.0% and 55.4% (APR/APR) and −47.6% and 52.0% (PBO/APR). For re-randomized pts who continued APR to Wk52, mean percent change in NAPSI was −59.7% ($n = 35$) and NAPSI-50 response rate was 63.2% (24/38). At Wk32, ScPGA 0 or 1 achievement was 32.4% (APR/APR) and 50.7% (PBO/APR); at Wk52 it was 54.1% (20/37, APR/APR/APR). At Wk32, PPPGA 0 or 1 achievement was 53.8% (APR/APR) and 69.2% (PBO/APR); at Wk52 it was 100.0% (4/4,APR/APR/APR). The most common AEs during the APR-exposure period (Wks0–52) were nausea, diarrhea, nasopharyngitis and URTI.

Conclusions: APR significantly improved nail, scalp and palmoplantar psoriasis at Wk16; improvements were sustained up to Wk52 for pts continuing APR from BL.

Disclosure of Interest: M. Gooderham Grant/Research support from: AbbVie, Allergan, Celgene, Eli Lilly, Galderma, Kythera, LEO Pharma, Merck, Novartis, and Pfizer, Speakers bureau of: AbbVie, Amgen, Astellas, Galderma, Janssen, LEO Pharma, Novartis, and Pfizer; J. Crowley Grant/Research support from: AbbVie, Amgen, AstraZeneca, Celgene, Janssen, Merck, Pfizer, and Regeneron, Consultant of: AbbVie, Amgen, and Celgene, Speakers bureau of: AbbVie; N. Wasel Grant/Research support from: Celgene; J. Weisman: None to declare; S. Tyring Grant/Research support from: Celgene; C. Hu Employee of: Celgene Corporation; R. Day Employee of: Celgene Corporation; C. Ferrandiz Consultant of: Celgene, Novartis, Janssen, and AbbVie.

Reference:

1. Kragballe K. Management of difficult to treat locations of psoriasis: scalp, face, flexures, palm/soles and nails. *Curr Prob Dermatol* 2009;38:160–171.

[P118] Table 1. Week 16 Results

	PBO	APR
NAPSI ⩾1, n*	84	163
NAPSI, mean % change	-7.1	-29.0§
NAPSI-50, %	18.7	44.6‡
ScPGA ⩾3, n*	93	176
ScPGA 0 or 1, %	17.2	40.9‡
PPPGA ⩾3, n*	16	26
PPPGA 0 or 1, %	31.3	65.4‖

*Includes patients with nail psoriasis (NAPSI ⩾1), or ScPGA⩾3, or PPPGA⩾3 at baseline and ⩾1 post-baseline value; Patients without a post-baseline value were counted as non-responders.§$P = 0.0052$ based on ANCOVA; ‡$P < 0.0001$ and ‖$P = 0.0315$ versus PBO, based on two-sided chi-square test.

P119

Physician perspectives in the management of psoriasis: Results from the population-based Multinational Assessment Of Psoriasis And Psoriatic Arthritis (MAPP) survey

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Introduction: The Multinational Assessment of Psoriasis and Psoriatic Arthritis (MAPP) is the largest, multinational, survey of patients and physicians conducted in North America (Canada, United States) and Europe (France, Germany, Italy, Spain, United Kingdom).

Objective: Obtain real-world perspectives on the impact of psoriasis and psoriatic arthritis (PsA) and its treatment.

Methods: Dermatologists and rheumatologists identified through national databases were contacted through random sampling methods.

Results: 6,530 dermatologists and 5,445 rheumatologists were screened; 391 and 390, respectively, completed interviews. Dermatologists estimated 33.0% of their psoriasis patients complaining of joint pain had a PsA diagnosis. Most respondents (>75%) agreed PsA is likely underdiagnosed due to failure to connect skin and joint symptoms. An impact on daily activities or social/emotional well-being was recognized by most physicians; 92.1% agreed disease burden is frequently underestimated. Location/size of skin lesions was selected as the most important factor contributing to psoriasis severity by 52.9% of dermatologists versus 17% of patients; 38% of patients selected itching as most important versus 7.4% of dermatologists. In patients with moderate/severe psoriasis, 74.9% were receiving topical therapy (alone or in combination with other therapies), 19.5% conventional oral therapy, and 19.6% biologics. In PsA patients, dermatologists and rheumatologists reported similar rates of biologic therapy (≈30%); conventional oral therapy was more often prescribed by rheumatologists (63.4%) versus dermatologists (35.2%). Reasons for not initiating or maintaining systemic therapies included long-term safety/tolerability, patient contraindications, lack of response, and cost (biologics).

Conclusion: Physicians caring for psoriasis and PsA patients acknowledge unmet treatment needs, largely concerning long-term safety/tolerability and efficacy of available therapies. Evidence suggests underdetection of PsA and undertreatment of psoriasis among dermatologists, and a need to acknowledge the importance of pruritus to patients when assessing disease severity and treatment options. A manuscript with these findings is currently in press: van de Kerkhof PCM, *et al.* J Eur Acad Dermatol Venereol. 2015. DOI: 10.1111/jdv.131.

Disclosure of Interest: P. Van de Kerkhof Consultant of: AbbVie, Allmirall, Amgen, Celgene, Centocor, Eli Lilly, Galderma, Janssen-Cilag, LEO Pharma, Mitsubishi, Novartis, Pfizer, Philips, and Sandoz; K. Reich Consultant of: Abbott, Biogen-Idec, Centocor, Janssen-Cilag, Schering-Plough, and Wyeth; A. Kavanaugh Consultant of: AbbVie, Amgen, Bristol-Myers Squibb, Celgene, Janssen, and UCB; G. Girolomoni Consultant of: AbbVie, Actelion, Boehringer Ingelheim, Celgene, Dompè, Eli Lilly, Galderma, Janssen, LEO Pharma, Maruho, Merck-Serono, MSD, Mundipharma, Novartis, Otsuka, Pfizer, Rottapharm, and Shiseido; H. Bachelez Consultant of: AbbVie, Almirall, Amgen, Boehringer Ingelheim, Celgene, Centocor, Eli Lilly, Janssen-Cilag, LEO Pharma, MSD, Merck-Serono, Novartis, Pfizer, Sandoz, and Takeda; C. Paul Consultant of: Abbott, Amgen, Astellas, Celgene, Janssen-Cilag, LEO Pharma, Novartis, Pfizer, and Pierre Fabre; J. Barker Grant/Research support from: AbbVie, Amgen, Celgene, Centocor, Eli Lilly, Janssen, Merck, Novartis, and Pfizer, Consultant of: AbbVie, Amgen, Celgene, Centocor, Eli Lilly, Janssen, Merck, Novartis, and Pfizer; R. Langley Consultant of: Abbott, Amgen, Centocor, and Schering-Plough; L. Puig Consultant of: Abbott, Amgen, Celgene, Centocor, Janssen-Cilag, LEO Pharma, Merck, MSD, Novartis, and Pfizer; M. Lebwohl Consultant of: Abbott, Amgen, Anacor, BioLineRx, Celgene, DermiPsor, Eli Lilly, Galderma, Janssen Biotech, LEO Pharma, Maruho, Meda, Novartis, Pfizer, and Valeant, Amgen, Celgene, Coronado Biosciences, Eli Lilly, GlaxoSmithKline, Janssen Biotech, LEO Pharma, and Ranbaxy.

P120

Apremilast, an oral phosphodiesterase 4 inhibitor, is associated with long-term (104-week) improvements in enthesitis and dactylitis in patients with psoriatic arthritis: Pooled results from three phase 3, randomized, controlled trials

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Introduction: Apremilast (APR) helps regulate immune responses in psoriatic arthritis (PsA). PALACE 1–3 compared APR efficacy and safety with placebo (PBO) in patients with active PsA despite prior conventional DMARDs and/or biologics, including efficacy assessment across multiple disease aspects. Enthesitis and dactylitis, hallmarks of PsA, lead to pain and disability.

Objective: Evaluate the impact of APR on enthesitis and dactylitis over 104 weeks in a pooled analysis of PALACE 1–3.

Methods: Patients were randomized (1:1:1) to PBO, APR 20 mg BID (APR20), or APR 30 mg BID (APR30) stratified by baseline (BL) DMARD use (yes/no). The PBO-controlled phase went to Week 24. Double-blind APR treatment continued to Week 52; patients could continue APR for up to 4 additional years. Data pooled across PALACE 1–3 allowed analysis of robust numbers of patients with pre-existing enthesopathy and/or dactylitis. Enthesitis was evaluated based on Maastricht Ankylosing Spondylitis Enthesitis Scores (MASES; 0–13), indicating the number of painful entheses out of 13 sites of entheses. Dactylitis count (0–20) is the number of digits (hands/feet) with dactylitis (each digit rated as 0 [none] or 1 [present]).

Results: Long-term improvement in BL enthesitis and dactylitis severity was seen in patients receiving APR at 104 weeks, as shown by MASES and dactylitis count reductions. BL MASES were 4.3 (APR30) and 4.6 (APR20). MASES mean changes were −57.5%/-55.1% (APR30/APR20) at Week 104. A MASES score = 0 (no pain at any assessed entheses) was achieved by 48.7%/51.5% (APR30/APR20) of patients. Dactylitis counts at BL were 3.4 (APR30) and 3.2 (APR20). Mean changes in dactylitis count were −80.0%/-75.8% (APR30/APR20) at Week 104; dactylitis counts decreased to 0 in 77.5%/72.9% (APR30/APR20) of patients. Over 104 weeks, most adverse events were mild/moderate; in general, no increase was seen in adverse event incidence/severity with longer term exposure.

Disclosure of Interest: D. Gladman Consultant of: AbbVie, Amgen, Bristol-Myers Squibb, Celgene Corporation, Janssen, Pfizer Inc, Novartis, and UCB; A. Kavanaugh Grant/Research support from: Abbott, Amgen, Astra-Zeneca, Bristol-Myers Squibb, Celgene Corporation, Centocor-Janssen, Pfizer Inc, Roche, and UCB; A. Adebajo: None to declare; J. Gomez-Reino Grant/Research support from: Roche and Schering-Plough, Consultant of: Bristol-Myers Squibb, Pfizer Inc, Roche, Schering-Plough, and UCB SA, Speakers bureau of: Bristol-Myers Squibb, Roche, Schering-Plough, and Wyeth; J. Wollenhaupt Grant/Research support from: Abbott, Bristol-Myers Squibb, MSD, Pfizer Inc, and UCB; M. Cutolo Grant/Research support from: Actelion, Bristol-Myers Squibb, and Sanofi-Aventis; G. Schett Grant/Research support from: Abbott, Celgene Corporation, Roche, and UCB; E. Lespessailles Grant/Research support from: Amgen, Eli Lilly, Novartis, and Servier; M. McIlraith Employee of: Celgene Corporation; C. Hu Employee of: Celgene Corporation; C. Edwards Grant/Research support from: Celgene Corporation, Pfizer Inc, Roche, and Samsung, Speakers bureau of: Abbott, Glaxo-SmithKline, Pfizer Inc, and Roche; C. Birbara Grant/Research support from: Amgen, Bristol-Myers Squibb, Incyte, Eli Lilly, Merck, and Pfizer Inc; P. Mease Grant/Research support from: Abbott, Amgen, Biogen Idec, Bristol-Myers Squibb, Genentech, Janssen, Eli Lilly, Pfizer Inc, and UCB, Consultant of: Celgene Corporation, Novartis, and Roche.

QUALITY OF LIFE

P122

Factors affecting the quality of life of people with psoriasis

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Introduction: The quality of life of patients suffering from psoriasis, is determined not only clinical manifestations of dermatosis, frequency of exacerbations, decreased social activity, but mental condition of patients. Research on quality of life of patients with psoriasis were emphasized mainly on the role of individual manifestations of disease in the decline in the quality of life of patients, it was not possible to differentiate the treatment of the patient depending on the available factors in varying degrees on the quality of his life. In this regard, the objective was to investigate the factors influencing the quality of life of people with psoriasis and their effects.

Methods: It was surveyed, 1090 people with psoriasis. We conducted a statistical analysis.

Results: The strongest impact on the quality of life of patients with psoriasis has a frequency of exacerbations. In second place is gender and comorbidities. Psoriatic arthritis is ranked 4th. And the least influenced by the age and duration of disease. Factors affecting quality of life (the degree of influence on the coefficient Cramer): frequency of exacerbations 0,41; gender 0,23; presence of concomitant diseases 0,2; psoriatic arthritis 0,19; age 0.08; the disease duration 0.07. With the increase in the frequency of exacerbations quality of life in 48.7% and decreases and reaches its lowest level during the course of the disease with constant relapses. Women with satisfactory and low quality of life in 2,5 times more than men. Among patients with concomitant low and satisfactory quality of life was recorded almost in 2 times more often than those without comorbidity. Unsatisfactory quality of life in patients with psoriatic arthritis (17.9 %) occurs 4 times more often than patients without arthritis. Patient age 45 years and older is a real risk of reduced quality of life. After 20 years of illness number of people with a low quality of life increases up to a quarter.

Conclusions: In the formation of risk groups should consider the factors that worsen the quality of life of patients.

Disclosure of Interest: None to declare.

P121

Formulation of Herbal Cream For Psoriasis Treatment and Its Symptoms Inhibition

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Psoriasis is a chronic and inflammatory multi-factorial disease which effects on elbow, knees, scalp etc. For psoriasis treatment, topical chemical agents are applied, in spite of inefficient effects or less effectiveness.The aim of this research is the making of new herbal cream for treating psoriasis. In the mentioned cream, extracts of medicinal herbal were formulated with vitamins (E, D3, B5, C, F) to apply on damaged skin. Some of these extracts include: SantalumAlbum,ArctiumLappa, MatricariaChamomilla, GlycyrrhizaGlobar, LavandulaAngustifolia, AvenaSativa, AloeBarbadesis, PinusEldarica,CydoniaSeed-Mucus. Cream was prepared by mixing water-in-oil(W/O). So, each phases were heated (70° C). Then aqueous phase was added to oily and were completely stirred until converted to cream form. Product as treatment cream, was proposed to 5 patients who suffer from psoriasis. Results were remarkable. All 5 patients were satisfied from itching inhibition and skin inflammation in first week. After 2 weeks applying cream, fading skin redness and increasing skin flexibility and repair were noticeable. An important point in this cream is the combining herbal extracts and vitamins that have high effectiveness than each alone. In fact, S.Album and L.Angustifolia were caused softening of skin corneous layer. Flavonoids and tannins in G.Globra, A.Lappa, P.Eldarica and A.Sativa are effective for treating skin lesions like psoriasis. Polysaccharides in A.Barbadensis and mucilage in C.seed-Mucus not only are healing skin wounds but also their malicacid make peeling skin dead cells. Moreover, pectin and pro-vitamins (A) act as antioxidants and prevent damage of skin healthy cells. Herbal β-sitosterols are factor of fading skin redness and anti-itching, α-bisabolol (M.Chamomilla)as anti-inflammation; blocks cyclooxygenase enzymes and inhibits leukotriene formation to prevent redness. In fact,this treatment cream is effective for collagen-synthesis, wound-improvement, epidermal-moisture maintenance, inflammation relief, boost immune-system and will inhibit psoriasis common symptoms in shortest time and no side effect.

Disclosure of Interest: None to declare.

P123

Identifying drivers of distress in psoriatic arthritis

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Introduction: Around 30% of people with psoriasis develop psoriatic arthritis (PsA). PsA can substantially impact upon quality of life and for patients with psoriasis significant distress and suicidal thoughts are well documented. People with PsA are also susceptible to distress from their condition but we know little about the additional burden of living with psoriasis and arthritis.

Objective: Identify the factors including illness and treatment beliefs associated with the distress of living with PsA.

Methods: Adults ($n = 23$) diagnosed with PsA participated in an in-depth qualitative study. Questions were informed by an established psychological model, the Common-Sense-Self-Regulatory Model (CS-SRM, Leventhal *et al.* 1984) enabling exploration of core beliefs and emotions related to living with PsA. Audio-recorded data were transcribed verbatim. Framework Analysis was used to categorise beliefs and emotions consistent with the CS-SRM from the data.

Results: Emergent themes include: 1. Consequences. Physical restrictions of PsA led to frustration and hopelessness. Patients feared their functioning would deteriorate progressively, jeopardising their independence. 2. The influence of others. Experiences of support varied and patients described that others (including health professionals) often don't take their condition seriously. 3. Put up and shut up. Patients actively hid their distress from those around them (again including health professionals). 4. Why me? Patients felt a deep sense of injustice, describing how PsA threatened their identity and often made negative comparisons with others.

Conclusions: High levels of distress including suicidal ideation exist for PsA patients. Salient emotions (eg fear), beliefs (eg I should cope with PsA alone) and misunderstandings (eg my functioning will deteriorate exponentially) about PsA, should be addressed within consultations to optimise management approaches.

Disclosure of Interest: None to declare.

P124

Effectiveness of adalimumab in the treatment of scalp and nail affection in patients with moderate to severe plaque psoriasis in routine clinical practice

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Introduction: Efficacy and safety of adalimumab (ADA) treatment for moderate/severe plaque psoriasis (PSO) has been demonstrated by several clinical trials but there is a lack of data on effectiveness of ADA in treatment of nail and scalp psoriatic lesions in routine clinical practice.

Objectives: The primary objective of this prospective, multi-country, observational study was evaluation of scalp and nail psoriasis improvement with ADA treatment over a period of 12 months. Secondary objectives included the evaluation of general improvement of psoriasis, assessment of changes in the quality of life (QoL) and evaluation of the association between general and nail or scalp improvement while on ADA therapy, and evaluation of the association between general, nail or scalp improvement and QoL.

Methods: 501 patients were analysed in the study. Of these, 157 patients had nail involvement (nail PSO set; NPS) and 404 had scalp involvement (scalp PSO set; SPS); with an overlap of 119 patients. For the analysis of the study objectives the Nail Psoriasis Severity Index (NAPSI), the Psoriasis Scalp Severity Index (PSSI), the Psoriasis Area and Severity Index (PASI) and the Dermatology Life Quality Index (DLQI) were applied.

Results: 84.0% of patients in NPS and 93.8% in SPS achieved clinical response (improvement of NAPSI or PSSI of at least 50%) by treatment with ADA at the study end. 33.3% of the patients with nail and 66.7% of the patients with scalp involvement experienced complete clearing of local symptoms. 65.3% of all patients achieved at least PASI90. There was also a marked improvement in QoL with ADA treatment and a moderate to strong association between general, nail or scalp improvement and QoL. During the study course 9.6% of the patients had an adverse event (AE) and 6.0% an adverse drug reaction (ADR—AE with possible/probable causal relationship to the study drug).

Conclusion: ADA appears to be effective treatment of scalp and nail PSO in patients with moderate/severe plaque PSO, improving both objective clinical indexes and QoL of the patients. No new clinical concerns were established or new safety signals observed in the study.

Disclosure of Interest: M. Bohinc Employee of: Abbvie; D. E. Branisteanu Consultant of: Antibiotice SA, Ivatherm, Fiterman, Speakers bureau of: AbbVie, AlfaWasserman, GSK, Janssen, Sanofi, Leo Pharma; K. Khobzey Speakers bureau of: Abbvie/Abbott, MSD, Astellas, GlaxoSmithKline; K. Kingo: None to declare; L. Pavlovsky Consultant of: AbbVie, Janssen, Pfizer, Novartis, Speakers bureau of: AbbVie, Janssen, Pfizer; J. Péč Grant/Research support from: AbbVie, Janssen, Pfizer, Teva and Nordic Pharma, Consultant of: AbbVie, Janssen, Pfizer, Teva and Nordic Pharma, Speakers bureau of: AbbVie, Janssen, Pfizer, Teva and Nordic Pharma; A. Szegedi Consultant of: AbbVie, MSD, Janssen, Pfizer, Speakers bureau of: AbbVie, MSD, Janssen, Pfizer; J. Miljković Shareholder of: Abbvie, Speakers bureau of: Abbvie.

P125

Differences in patient reported psoriasis symptom severity between patients rated as 'clear' versus 'almost clear' based on Physician Global Assessment

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Introduction: Physicians routinely assess psoriasis severity with the static Physician's Global Assessment [sPGA, 0 (clear of disease) to 5 (very severe disease)]. Response to treatment is typically defined as achieving sPGA 0 or 1 (almost clear). Patients' perception of the difference between sPGA 0 and 1 is not fully understood.

Objectives: To compare psoriasis symptom severity between sPGA 0 and sPGA 1 using the patient reported Psoriasis Symptom Inventory (PSI).

Methods: This cross-sectional, observational study enrolled adult patients with moderate to severe psoriasis receiving a biologic. Patients completed the 8-item PSI electronic daily diary on 7 consecutive days (Day 1–7; total score calculated as the average of ≥ 4 daily scores). Each item is scored on a 5 point scale from 0 (not at all severe) to 5 (very severe). Physician reported sPGA and Psoriasis Area and Severity Index (PASI) scores were collected at the entry (Day 1) and exit visits (Day 8–11). Patients with a change in sPGA status between these visits were excluded. Two-by-two cross-tabulations with Pearson chi-square were used to compare sPGA 0 and sPGA 1 based on PSI score thresholds [PSI = 0 versus PSI > 0 and PSI responder (PSI $\leq$ 8, no single item > 1) versus others].

Results: Of the 295 patients enrolled, 230 were included in the analysis (excluded: 62 for sPGA changes between entry and exit visits, 3 for incomplete PSI data). Mean age was 48 years; 46% of patients were female; 87% were white; 79 patients had sPGA 0 and 151 had sPGA 1 (mean PASI: 0.009 and 1.67, respectively). Compared with patients rated as 'almost clear' (sPGA 1), a significantly higher proportion of patients with skin clearance (sPGA 0) reported no psoriasis symptom severity (PSI 0), and achieved PSI responder status, ie reported all eight PSI signs and symptoms to be 0 or 1 (mild) (Table).

Conclusions: When compared with patients rated as 'almost clear' based on physician assessments, significantly more patients rated as 'clear' reported either no severity or lower severity of psoriasis signs and symptoms.

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[P125] Table 1. PSI summarized by sPGA

	sPGA 0 ($n = 79$)	sPGA 1 ($n = 151$)	*P*-value
PSI 0, %	60.8	5.3	<0.001
PSI responder, %	94.9	54.3	<0.001

P126

Manifest for psoriasis

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Introduction: Psoriasis is a chronic & systemic disease that affects 2–4% of world population & 300,000 people in Portugal. The impact on quality of life is very high; some authors consider that its burden is superior when compared with diseases like cancer & arthritis. The low knowledge about psoriasis is very high leading to discriminatory situations. Patients tend to hide, retrieving themselves from public exposure, professional & social life (depression and social isolation).

Objectives: Increase awareness about psoriasis by demystifying the disease: Demystify psoriatic disease; Activate to seek a physician; Awareness among GP's in order to early diagnose & referral process to dermatology. Elevate PSOPortugal (Portuguese patient association) in order to increase patient help & support.

Methods: Partnership between dermatologists & PSO, a new disease awareness campaign was developed based on the manifest of patients and physicians, together with 2 public figures. The main goal is to demystify psoriasis under the claim *''Psoriasis?! Other things bother me much more!!!''* like discrimination, isolation, undertreatment, difficult access to therapies and dermatologists. A multi-channel disease awareness campaign, targeting patients & general population was initiated. A new website (www.manifestopelapsoriase.pt) is the center of the campaign, compiling educational information based on 3 pillars: *''To Know; To Accept; To Treat – ''Psoriasis: The real prey isn't only the skin''*. Here patients, physicians, friends can write or upload videos with their Manifest & obtain all the information needed to better understand this disease.

Results: See table.

Conclusions: Disease awareness and patient empowerment are key to increase the nr of early diagnosis, increase correct referral between specialists, decrease discrimination & leverage disease knowledge.

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[P126] Table 1

	06–11–2014	06–03–2015
FB Friends	2183	4854
Likes FB		12201
Comments FB Posts		925
Shares FB		2938
Rank FB Health Brands	116°	76°
Youtube		7356
site Views		19172
site Users		3491
TVtime		1 h 55 m

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Development of a patient-reported outcomes instrument for the measurement of treatment satisfaction in plaque psoriasis

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Introduction: While clinical assessments may assess disease severity in plaque psoriasis (Ps), many aspects of the Ps experience (eg, symptoms, quality of life impacts, treatment satisfaction) are best assessed by patients (pts).

Objective: To develop a new pt-centered instrument to evaluate treatment satisfaction in Ps.

Methods: A Medline literature search identified symptoms of Ps and pt-reported treatment satisfaction questionnaires used to evaluate Ps. A 2nd search queried Embase™, PsycINFO, ClinicalTrials.gov, and Patient-Reported Outcome and Quality of Life Instruments Database (PROQOLID). Both searches were limited to English-language studies in humans published within 10 years.

Concept elicitation (CE) interviews were then conducted with adult (⩾18 years of age) Ps pts. Interview transcripts were analyzed to identify pt-reported concepts characterizing treatment satisfaction. Based on CE results, short- and long-form questionnaires were constructed and subjected to pt cognitive debriefing interviews (CIs), which resulted in questionnaire revisions.

Results: 15 articles were reviewed in Search 1 and 11 abstracts in Search 2. Search 1 yielded 12 relevant symptoms (plaques, pain, itching, flaking, scaling, cracking, dry skin, burning/stinging, bleeding, redness, nail changes, and fatigue). Search 2 identified 6 treatment satisfaction questionnaires; however, only 1 was Ps-specific (the Psoriasis Subject Satisfaction Questionnaire). 10 patients (CE interviews: $n=5$; CIs: $n=5$) participated in qualitative interviews. Draft versions of questionnaires contained 9 and 13 items, respectively, and addressed concepts related to symptoms (eg, flaking, scaling, itching), impacts (eg, appearance, overall skin clearance), and treatment administration (eg, frequency, side effects). Following CIs, revisions to item wording, ordering, instructions, and response options were made; all items were retained.

Conclusions: Content validity of these 2 new measures of treatment satisfaction in pts with Ps was supported. Future work will focus on quantitative evaluation of the instrument in this population.

Disclosure of Interest: A. Armstrong Consultant of: AbbVie, Amgen, Janssen, Merck, Lilly, Celgene, Novartis, Pfizer, and Modernizing Medicine; M. Sundaram Shareholder of: AbbVie, Employee of: AbbVie; C. Foley Employee of: Adelphi Values, which received payment from AbbVie Inc. to assist with the research process; F. Pompilus Employee of: Adelphi Values, which received payment from AbbVie Inc. to assist with the research process; J. Stokes Employee of: Adelphi Values, which received payment from AbbVie Inc. to assist with the research process; A. Shields Employee of: Adelphi Values, which received payment from AbbVie Inc. to assist with the research process.

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Rasch analysis of the Health Assessment Questionnaire Disability Index in psoriatic arthritis

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Background: The cross-cultural validity of the Health Assessment Questionnaire Disability Index (HAQ-DI) in psoriatic arthritis (PSA) has not been well studied.

Objectives: To assess the validity of the HAQ-DI in PSA and determine its invariance to different patient characteristics including culture.

Methods: We analysed HAQ-DI data from patients with PsA in 5 cultural regions (the UK, N. America, S. America, Europe and Asia) using Rasch analysis to determine the scale's construct validity, person separation index (PSI) reliability, unidimensionality, targeting and the invariance of the scale across patient characteristics (culture, age, gender, disease duration, disease type and extent of skin involvement).

Results: The dataset comprised 503 patients (286 women) from 15 countries. Their mean (SD) age was 50.8 (13.1), psoriasis duration, 18.4 (13.7) years and PSA duration, 9.8 (9.9) years.

Table 1 presents the summary statistics for the overall model fit (χ^2 interaction) and reliability (PSI). The fit statistics suggest adequate fit to the model and acceptable reliability in all individual cultural groups and except S. America and Asia where sample sizes were limited (not shown).

The HAQ-DI was unidimensional and invariant to all personal characteristics in the N. America dataset. In the pooled dataset, the HAQ-DI displayed differential item functioning (DIF) by type of arthritis, where those with oligoarthritis were more likely to have lower scores on the dressing & grooming item than those with polyarthritis. Floor effects were evident, especially in oligoarthritis. Using the DIF-free population (N. America), the HAQ-DI was shown to be well-targeted and discriminated well between the two types of arthritis (graph not shown).

Conclusions: In Europe and N America, HAQ-DI is a cross-culturally valid and reliable measure of disability in PsA and Rasch-transformed values can be used with confidence alongside other outcome measures in parametric analyses.

Disclosure of Interest: M. Ndosi Grant/Research support from: Pfizer Inc; M.-A. Hsu Shareholder of: Pfizer Inc; J. C. Cappelleri Shareholder of: Pfizer Inc; H. Jones Shareholder of: Pfizer Inc; A. C. Amit Chhabra Shareholder of: Pfizer Inc; P. Helliwell Grant/Research support from: Pfizer Inc.

[P128] Table 1. Overall model fit statistics for HAQ-DI

Region	χ^2 interaction statistic (*P*-value)	PSI Reliability
UK	8.575 (0.379)	0.885
North America	5.299 (0.725)	0.860
Europe (excl UK)	25.356 (0.064)	0.855
Pooled	76.310 (0.037)	0.857

P129

Burden of flares on patients with moderate to severe psoriasis: results of the Adelphi Real World Psoriasis Disease Specific Programme in the United States

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Introduction: Patients (pts) with plaque psoriasis have periods of disease exacerbation (flares) and remission.

Objectives: To estimate the annual burden of flares on pts with moderate to severe psoriasis in the US.

Methods: This was a retrospective, cross-sectional analysis of survey data of pts with psoriasis treated by a dermatologist from Jan to Mar 2013 in the Adelphi Real World Psoriasis Disease Specific Programme. Flaring was defined as pts with current disease activity, with worsening/unstable disease progression, and included pts in remission ⩽12 weeks according to indicators of current disease activity. Flaring and non-flaring pts were matched for demographic and clinical covariates using a multivariate matching algorithm. Health-related quality of life (HRQoL) was assessed with the EuroQol-5D-3L (EQ-5D) using a Wilcoxon signed-rank test. Secondary endpoints, compared between all non-matched flaring and non-flaring pts using Wilcoxon rank sum or Fisher's exact tests, included Dermatology Life Quality Index (DLQI), Work Productivity and Activity Impairment (WPAI), physician-rated treatment satisfaction and clinical disease control.

Results: HRQoL, assessed in matched pts ($n=68$/group), was reduced in flaring versus non-flaring pts, with an EQ-5D effect size of -0.076; this was statistically significant ($P=0.001$) and clinically meaningful (⩾0.074 in absolute value). A total of 525 non-matched pts were included in secondary analyses. DLQI was greater in flaring ($n=142$) versus non-flaring ($n=383$) pts (median: 4.0 versus 3.0, respectively; $P=0.0178$), indicating worse HRQoL in flaring pts. The WPAI showed greater activity impairment in flaring versus non-flaring pts (median: 20% versus 10%, respectively, $P=0.0002$). More physicians were dissatisfied with disease control for flaring versus non-flaring pts (36.0% versus 7.1%, respectively; $P<0.0001$) and effectiveness of the current treatment (28.1% versus 10.5%, respectively; $P<0.0001$).

Conclusions: Compared with non-flaring pts, flaring pts experienced clinically meaningful worsening in HRQoL, assessed by EQ-5D and DLQI, and greater WPAI activity impairment. This study highlights the importance of controlling flares in reducing pt disease burden.

Disclosure of Interest: M.-A. Hsu Shareholder of: Pfizer Inc, Employee of: Pfizer Inc; J. Lucas Employee of: Adelphi Real World; R. Wood Employee of: Adelphi Real World; J. C. Cappelleri Shareholder of: Pfizer Inc, Employee of: Pfizer Inc; J. Piercy Employee of: Adelphi Real World; L. Mallbris Shareholder of: Pfizer Inc, Employee of: Pfizer Inc at the time of data analysis and abstract development; C. Mamolo Shareholder of: Pfizer Inc, Employee of: Pfizer Inc.

P130

Treatment patterns, clinical outcomes, and patient-reported outcomes among adults admitted to hospital in the United Kingdom (UK) due to plaque or erythrodermic psoriasis

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Introduction: No recent studies have assessed treatment patterns and outcomes among patients hospitalized for psoriasis in the UK.

Objectives: To evaluate treatment patterns, clinical and patient-reported outcomes in patients admitted to hospital for plaque or erythrodermic psoriasis.

Methods: Of 107 hospital stays across 9 hospitals, 61 eligible patients completed questionnaires at admission and discharge about their disease (symptoms, treatments, costs), health status (SF-12v2, EQ-5D-3L), dermatology-related quality of life (DLQI), and work productivity (WPAI). Sites recorded psoriasis treatments, length of stay (LOS), Psoriasis Area Severity Index (PASI), Body Surface Area (BSA), and Physician Global Assessment (PGA) scores at admission and discharge. Descriptive statistics are based on those responding to each item.

Results: Mean age was 45.5 years; 50.8% were male. Mean body mass index and time since diagnosis were 32.1 kg/m^2 and 20.0 years, respectively. The most common comorbid conditions were psoriatic arthritis (34.4%), depression (24.6%), and arterial hypertension (21.3%). Most (78.7%) had ⩾1 previous hospitalization for psoriasis. At admission, 44.9% reported changes in employment status due to psoriasis; among the 35.1% employed for pay, mean WPAI work impairment was 79.2%. Mean SF-12v2 Physical and Mental component summary scores were 35.4 and 32.1, respectively, indicating significant impairment. PASI, BSA, and PGA scores improved from admission to discharge (all $P<0.0001$), with 22.9% achieving PASI75. EQ-5D-3L, DLQI, and psoriasis symptom scores improved from admission to discharge (all $P<0.05$), however mean EQ-5D-3L at discharge was low (0.60). During hospitalization, patients received topicals (100%), systemic therapy (54.1%), phototherapy (23%), and/or biologicals (6.6%); 27.9% received only topicals. Mean (range) LOS was 17.0 (2,71) days; for patients achieving PASI75, mean LOS was 18.1 versus 13.1 days for those not achieving PASI75.

Conclusions: Although few patients are admitted for psoriasis, mean LOS was long for those hospitalized. On average, patients improved during the hospital stay; yet still reported suboptimal outcomes at discharge.

Disclosure of Interest: C. Schaefer Employee of: Covance Market Access Services Inc., which was engaged by Pfizer Inc. for study design, execution and analysis and for abstract development; C. Mamolo Shareholder of: Pfizer Inc., Employee of: Pfizer Inc.; J. Cappelleri Shareholder of: Pfizer Inc., Employee of: Pfizer Inc.; C. Le Employee of: Covance Market Access Services Inc., which was engaged by Pfizer Inc. for study design, execution and analysis and for abstract development; S. Daniel Employee of: Covance Market Access Services Inc., which was engaged by Pfizer Inc. for study design, execution and analysis and for abstract development; L. Mallbris Employee of: Pfizer Inc. at the time of the study and during abstract development.

P131

Development of a patient-reported outcomes instrument for the measurement of the sexual impacts of psoriasis

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Introduction: Psoriasis (Ps) is a chronic, immune-mediated skin disease that can significantly worsen quality of life (QoL). Several instruments are available to assess Ps patient (pt) well-being, but no tool has been developed to capture disease-related sexual and reproductive pt impacts.

Objective: To develop an instrument to measure the sexual impacts of Ps based on qualitative patient interviews.

Methods: 2 rounds of qualitative interviews—1) concept elicitation (CE) interviews; and 2) hybrid CE/cognitive interviews (CIs)—were conducted with Ps pts ⩾18 years old. Interview transcripts were analyzed to identify pt-reported impacts. Criteria for participation in both rounds of interviews differed only in that pts in the 2nd round had to self-report suffering from ⩾1 sexual impact.

2 sex-specific questionnaires, the Psoriasis Relationships and Sexual Impact Assessment-Male and -Female (PRSIA-M and PRSIA-F), were created after the 1st round of interviews. Items were selected based on the frequency with which a concept was reported and on clinical and pt-reported relevance. Hybrid interviews were then used to enumerate and affirm reported impacts, assess content validity, and revise questionnaires.

Results: 60 (round 1 [R1]: $n=40$; Round 2 [R2]: $n=20$) pts participated in qualitative interviews. Intimate impacts were reported by 68% ($n=27$) of pts in R1, and 24 distinct impacts were noted across both rounds. Impacts were categorized into 1 of 4 domains: Sexual Desire (R1: 23/27, 85%; R2: 20/20, 100%), Sexual Ability (R1: 17/27, 63%; R2: 20/20, 100%), Reproduction (R1: 5/27, 19%; R2: 20/20, 100%), and Relationships (R1: 17/27, 63%; R2: 20/20, 100%).

Each questionnaire initially included 20 items. After CIs, revisions to item wording, order, instructions, and response options were made; all items were retained.

Conclusions: Owing to the sensitive nature of the intimate impacts of Ps, these potentially devastating outcomes may not be routinely addressed in a clinical setting. The PRSIA instruments may facilitate dialogue between pts and clinicians, improve treatment, and aid in developing future Ps QoL assessments.

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P132

Psycho-social determinants of quality of life in psoriasis patients in developing countries

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Background: Numerous studies have analyzed the influence of psoriasis on the quality of life and psychological health of patients. However few studies have addressed the effect of this disease on individuals and cohabitants of psoriatic patients.

Objective: To assess the clinical severity, the physical and psychosocial disability and to analyze their interrelationship in psoriasis patients and cohabitants.

Methods: Hospital based cross-sectional study was conducted. The study included patients and cohabitants. The questionnaire was administered to the patient. Their quality of life was measured with the Psoriasis Disability index (PDI) and Family Dermatology Life Quality Index (FDLQI), and their psychological state with Psoriasis Life Stress Inventory (PLSI). The clinical severity by Psoriasis area severity index (PASI) score. Appropriate test were conducted using SPSS software.

Results: 75 patients (46 males, 29 female) were included in the study. The clinical PASI scores correlated significantly with the overall physical disability PDI (<0.0001), stress incurred PLSI (<0.0001), FDLQI (<0.0001) and individual aspects of the PDI. The higher the PASI index, the higher the PDI, PLSI and FDLQI scores, which indicated greater impact on QOL. Most of the patients feel depressed by the shedding of skin, avoid public places, constant fear of relapse and embarrassed in social interaction. Among the physical and psychosocial factors analyzed, daily activity, employment, leisure and treatment were reported to be affected the most. Relative of female patients worries most. Mean scores Female: Male of FDLQI (13.3 : 10.3).

Conclusions: Psoriasis markedly worsens the global well-being of patients and their cohabitants, who experienced an impairment of their quality of life and higher levels of anxiety and depression.

Disclosure of Interest: None to declare.

P133

The relevance of total skin clearance for patients with plaque psoriasis: A comparison of health related quality of life benefits associated with achieving PASI100 versus PASI90 to <100, and PASI75 to <90

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Introduction: A 75% improvement in the psoriasis area and severity index (PASI75) is a common clinical trial endpoint in psoriasis (PsO). New therapies have demonstrated a significant number of patients achieving almost clear skin (PASI90) and even total skin clearance (PASI100). The difference between achieving higher levels of skin clearance in terms of health-related quality of life is not well understood.

Objectives: To compare health related quality of life (HRQoL) differences associated with achieving PASI100 versus PASI90 to <100, and PASI75 to <90 using RCT data.

Methods: Data from all non-placebo arms of 3 brodalumab Phase III PsO studies (NCT01708590, NCT01708603, and NCT01708629) were pooled. Analyses compared proportions of patients achieving a dermatology life quality index (DLQI) total score of 0 or 1 (no effect on HRQoL) at Week 12, among patients achieving PASI100, PASI90 to <100, PASI75 to <90, and PASI75 to <100.

Results: Baseline DLQI scores were similar across patients who achieved PASI100 (baseline mean DLQI = 14.0, SD = 7.0) and PASI75 to <100 (baseline mean DLQI = 14.6, SD = 7.3) at Week 12. 1078, 906 and 594 patients achieved PASI100, PASI90 to <100, and PASI75 to <90 with non-missing DLQI score at week 12, respectively. A significantly higher percentage (95% CI) of patients with PASI100 [80.2%, (77.7%, 82.6%)] achieved DLQI = 0/1 compared to PASI90 to <100 [62.7%, (59.5%, 65.9%)], PASI75 to <90 [42.9%, (38.9%, 47.0%)], and PASI75 to <100 [54.9%, (52.3%, 57.4%)], all $P<0.001$.

Conclusions: A significantly higher proportion of patients achieving complete psoriasis clearance (PASI100) reported no effect on HRQoL compared to those achieving PASI90 to <100 or PASI75 to <90. Results showed meaningful HRQoL differences between achieving PASI100 versus PASI90 to <100, or PASI75 to <90 in the clinical trial population of subjects with moderate to severe chronic plaque psoriasis. The findings support the use of PASI100 as a differentiating, clinically relevant endpoint in addition to PASI90 and PASI75.

Disclosure of Interest: M. Augustin Consultant of: Amgen; K. Reich Consultant of: Amgen; C. Paul Consultant of: Amgen; M. Lebwohl Consultant of: Amgen; C. E. Milmont Shareholder of: Amgen, Employee of: Amgen; H. N. Viswanathan Shareholder of: Amgen, Employee of: Amgen; A. Mutebi Shareholder of: Amgen, Employee of: Amgen; P. Klekotka Shareholder of: Amgen, Employee of: Amgen.

P134

Ixekizumab impact on health-related quality of life compared to etanercept and placebo: Results from UNCOVER-2, a phase 3 trial in patients with moderate-to-severe plaque psoriasis

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Introduction: Psoriasis has a significant impact on health-related quality of life (HRQoL).

Objectives: To understand the impact on HRQoL after 12 weeks of treatment with ixekizumab, an anti-IL-17A monoclonal antibody, compared to etanercept or placebo.

Methods: In this trial, 1,224 patients were randomized to receive subcutaneous placebo ($N=168$), etanercept (50 mg twice weekly; $N=358$), or a single injection of 80 mg ixekizumab every 2 weeks (IXE Q2W; $N=351$) or every 4 weeks (IXE Q4W; $N=347$) following a 160 mg starting dose at week 0. HRQoL was assessed with the Dermatology Life Quality Index (DLQI) and the SF-36. DLQI scores of 0 or 1 indicate no impact of skin disease on HRQoL. The SF-36 Physical (PCS) and Mental (MCS) component summary scores are derived from the eight SF-36 domains (scored 0–100). The proportion of patients who achieved a DLQI score of 0 or 1 at week 12 and changes in DLQI total score, PCS, and MCS scores from baseline to week 12 were compared between treatment groups.

Results: The average baseline DLQI score across groups was 12.3 and the average baseline SF-36 MCS and PCS were 48.3 and 47.6, respectively. Greater improvements in DLQI were observed as early as first postbaseline assessment at week 2 for the ixekizumab treatment groups compared to placebo and etanercept ($P<0.05$). At week 12, more patients in the IXE Q2W (64%) and IXE Q4W (60%) groups had a DLQI score of 0 or 1 versus placebo (6%; $P<0.05$) or etanercept (34%; $P<0.05$). At week 12, greater improvements in the SF-36 PCS were observed in the IXE Q2W (3.8) and IXE Q4W (4.6) groups versus placebo (-0.5; $P<0.05$) and etanercept (2.6; $P<0.05$). There were greater improvements in the SF-36 MCS in the IXE Q2W (4.5) and IXE Q4W (2.9) groups versus placebo (-0.1; $P<0.05$) and in the IXE Q2W group versus etanercept (2.4; $P<0.05$).

Conclusions: Ixekizumab-treated patients reported significantly greater and more rapid improvements in HRQoL as measured by DLQI or SF-36 compared to placebo and etanercept over 12 weeks, and more than 60% patients reported no impact of psoriasis on HRQoL with a DLQI score of 0 or 1.

Disclosure of Interest: K. Reich Consultant of: AbbVie, Amgen, Biogen-Idec, Celgene, Centocor, Covagen, Eli Lilly, Forward Pharma, GlaxoSmithKline, Janssen-Cilag, LEO Pharma, Medac, MSD, Novartis, Ocean Pharma, Pfizer, Regeneron, Takeda, UCB, Vertex, Xenoport, Speakers bureau of: AbbVie, Amgen, Biogen-Idec, Celgene, Centocor, Covagen, Eli Lilly, Forward Pharma, GlaxoSmithKline, Janssen-Cilag, LEO Pharma, Medac, MSD, Novartis, Ocean Pharma, Pfizer, Regeneron, Takeda, UCB, Vertex, Xenoport; D. Toth Grant/Research support from: LEO, Celgene, Amgen, Janssen, Lilly, Novartis, Pfizer, Abbott, Speakers bureau of: Lilly, Novartis, Amgen, Janssen, Celgene, Abbott; E. Nikai Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company; B. Zhu Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company; H. Carlier Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company; S. Feldman Shareholder of: Medical Quality Enhancement Corporation, Causa Research, Grant/Research support from: Galderma, National Biological Corporation, Anacor, Novartis, Pfizer, Consultant of: Celgene, Mylan, GSK/Stiefel, Amgen, Novartis, Lilly, Speakers bureau of: Galderma, Janssen, Novartis, Celgene, Abbvie, Pfizer, Baxter, Merck, Boehringer Ingelheim.

P135

Effect of etanercept on patient-reported outcomes in psoriasis patients with and without metabolic syndrome

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Introduction: Psoriasis patients have higher rates of metabolic syndrome (MetS) and impaired quality of life.

Objective: To compare the effect of etanercept on patient-reported outcomes (PROs) in psoriasis patients with MetS and without MetS (non-MetS).

Methods: Changes from baseline to week 24 in PROs were compared using ANCOVA models adjusted for baseline PRO and geographic region; week 24 dichotomous responses were analyzed using Fisher's exact test. Baseline continuous and categorical variables were analyzed using Wilcoxon-Mann-Whitney and Cochran-Mantel-Haenszel tests, respectively. Baseline characteristics and week 24 data were analyzed using the randomized population and modified intent-to-treat population, respectively.

Results: 121 patients from the PRISTINE trial met MetS criteria. Patients received etanercept 50 mg subcutaneously once weekly (QW) or twice weekly (BIW) for 12 weeks followed by etanercept 50 mg QW for another 12 weeks. Statistically significant higher baseline values for MetS parameters were observed for MetS patients compared with non-MetS patients with no differences seen for PASI or PROs; non-MetS patients were younger and had statistically significant higher HDL levels. In the QW/QW group, week 24 changes between MetS and non-MetS patients for EQ-5D Usual Activity and WPAI Work Time Missed were statistically significant (–0.06 versus −0.34, $P<0.001$, and −7.38 versus −5.45, $P<0.05$, respectively). Numerically greater week 24 improvement was observed in non-MetS patients for FACIT-Fatigue, HADS, and various domains of DLQI, EQ-5D, Patient Global Assessment, and WPAI. More non-MetS patients had DLQI improvement ⩾5 and fewer patients had major HADS anxiety (⩾11) and depression (⩾11) at week 24.

Conclusions: At baseline, the MetS group had more comorbidities. Observed PRO responses at week 24 were better for non-MetS patients than for MetS patients. Since no adjustment was made for multiple comparisons, statistically significant findings should be considered exploratory.

Limitations: This post-hoc analysis used data from a previously completed trial that was not designed with sufficient power to detect differences in PROs.

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Rasch analysis of the Psoriatic Arthritis Quality of Life and Dermatology Life Quality Index measures in psoriatic arthritis

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Background: Psoriatic Arthritis Quality of Life (PsAQol) and Dermatology Life Quality Index (DLQI) measures cover different aspects of psoriatic arthritis (PsA) but the ability of each measure to capture health-related quality of life information about skin and joint disease simultaneously is unknown.

Objectives: To assess cross-cultural validity of the PsAQoL and DLQI and to determine if each measure captures domains relevant to both skin and joints.

Methods: PsAQoL and DLQI data from people with PsA in 5 cultural regions (UK, N. America, S. America, Europe and Asia) were analysed using Rasch analysis to determine their construct validity, reliability, targeting and invariance to culture, gender, age and disease duration; disease type and extent of skin involvement (PASI score split at 10).

Results: The sample comprised 503 patients (286 were women) with mean (SD) age 50.8 (13.1), psoriasis duration 18.4 (13.7) and PSA duration 9.8 (9.9) years.

The N. America PsAQoL and DLQI data satisfied the expectations of the Rasch model while the Europe and pooled data did not. See table 1 (Asia and S. America had limited sample sizes—not shown).

Within each cultural group, PsAQoL was invariant to all patient characteristics. For the DLQI, the N. America data displayed DIF by gender on items 8 & 9. The pooled data displayed DIF by culture on items 1 and 7 and DIF by gender on item 4.

Both PsAQoL and DLQI discriminated well between patients with oligo/polyarthritis. As expected, DLQI discriminated well between the patients with high versus low degree of skin involvement but the PsAQoL did not.

Conclusions: There is not enough evidence from this analysis to suggest the cross-cultural validity of the PsAQoL and DLQI or whether each measure captures domains relevant to both skin and joints.

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[P136] Table 1. Summary statistics and reliability of the PsAQoL and the DLQI

Region	PsAQoL χ^2 interaction statistic (*P*-value)	PsAQoL reliability (PSI)	DLQI χ^2 interaction statistic (*P*-value)	DLQI reliability (PSI)
UK	38.481 (0.008)	0.870	14.227 (0.163)	0.819
N. America	25.385 (0.187)	0.887	15.638 (0.111)	0.781
Europe (excl UK)	56.882 (0.040)	0.826	24.221 (0.007)	0.825
Pooled data	202.392 (0.001)	0.851	167.741 (<0.001)	0.803

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Education is key to building a better world for people with psoriasis

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Introduction: In 2014 it was decided that IFPA should seek to identify strategic activities, or ''tools'', to help improve the situation for people with psoriasis world-wide, by conducting an online open survey. 17 such activities were selected and the survey went live June 8, 2014 and will close May 31, 2015.

Objectives: To identify which strategic activities within psoriasis education, awareness and advocacy patients, their family members, physicians and others believe to be the most important; acting as guidance for all psoriasis stakeholders addressing unmet needs.

Methods: The 17 ''tools'' were developed into an online survey which was then linked into IFPA's website as a pop-up window. The survey is anonymous, but the respondents are asked to identify respondent category, gender, age group and country. The respondents can vote for up to five ''tools'' and also add their own free-text suggestion.

Results: The survey was accessed on March 6, 10 am CET. The activities receiving the most votes from the patient category ($n=1{,}116$), with respondents from 88 countries, at this point were: ''Tool 2: Educating the patients about treatment options'' (53%), ''Tool 3: Educating the patients about serious comorbid conditions'' (42%) and ''Tool 1: Educating the patients about psoriasis as a serious, inflammatory, noncommunicable disease'' (38%). In the physician group ($n=156$) 55 countries were represented. The most votes from the physician category went to Tool 3 (58%), Tool 1 (56%) and Tool 2 (55%). The top three votes of the family member group ($n=182$), representing 50 countries, went to Tool 2 (49%), Tool 1 (45%) and Tool 3 (36%). In the category ''Other'' we find primarily other HCPs, pharma professionals, pharmacists, researchers, volunteers and friends. This category had 196 respondents from 55 countries and the top votes were for Tool 2 (46%), Tool 3 (42%) and Tool 9: ''Educating policy makers about the socioeconomic and psychosocial impact of psoriasis'' (41%).

Conclusion: Of the activities suggested in the survey, these preliminary results clearly indicate that all respondent categories see primarily educational initiatives as key to improving the situation for people with psoriasis.

Disclosure of Interest: None to declare.

YOUNG SCIENTISTS (BORN ON OR AFTER JANUARY 1, 1980)

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Need psoriasis patients in the event of medico-social nature, necessary to improve the quality of medical care

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Introduction: The level of patient satisfaction with medical help becomes a key criterion not only to improve the quality and accessibility of medical care, learning needs of the population, but also a tool to enhance the social role of health in shaping public consciousness. In this regard, the objective is to highlight the needs of patients in the activities of the specialized service.

Methods: It was surveyed 1,090 people with psoriasis. We conducted a statistical analysis.

Results: Marked low (not exceeding 2.5 points at the 5-point system) level estimates of the impact of medical measures to improve the status and improving the quality of life of patients. However, priority is given to the possibility of obtaining psychological help to improve the interaction between various specialists involved in the treatment of patients, clinical monitoring, provision of sanatorium-resort treatment, enhancing patient participation in the treatment process. The remaining proposed for the evaluation of patients events related to the organization of work of the doctor and are not of interest to patients. The last place in the ranking took the importance of establishing interaction with the doctor, which can be explained by the absence of this problem in most patients. According to patients, most of them need a number of events non-medical plan and measures of public support. Among the measures medical priority given to greater involvement of relatives to support patients, the patients Association in non-governmental organizations on the disease profile, the expansion of the Internet in advising patients and their immediate environment.

Conclusions: The provision of quality medical care, taking into account the complexity of its rendering in importance is not inferior to the needs of patients and to ensure their measures of social support in the prevailing situation, which should be aimed at attracting relatives to the treatment process, the formation of partnerships with patients, joint definition of the treatment programs, the creation and involvement of the patient in the patient's community profile of the disease, the possibility of online communication with experts.

Disclosure of Interest: None to declare.

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Psoriatic arthritis and the heavy lung heredity

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Introduction: Our understanding of psoriatic arthritis has evolved, as a new knowledge of the disease has emerged, defining it as a chronic inflammatory systemic disorder. Epidemiological studies summarized several comorbidities,[1] but the results of studies on respiratory comorbidities are discordant.[2]

Objectives: Psoriatic arthritis is a pro-inflammatory condition, importantly assessed in blood, urine and synovial fluid. In this study we aimed to evaluate the sub-clinical airway inflammation in non-smoking psoriatic people with FeNO (Fraction of exhaled nitric oxide), an indirect marker of inflammation, in order to evaluate the respiratory risk of respiratory comorbidities in psoriasis.

Methods: A sample of 57 non-smoking patients with psoriatic arthritis (satisfying CASPAR classification criteria) were recruited and compared with a control group of 57 psoriatic patients. A respiratory evaluation was preliminary performed with a spirometric exam, that pointed as inclusion criteria a BMI<25, Tiffenau Index >70%, FEV1>80%, FEF 25–75 >65%, no active respiratory diseases and lung cancer history. Then after one-week discontinuation therapy, included patients performed FeNO test with on-line single-breath technique. Different flows (30,50,100,200 ml/sec) were adopted in order to evaluate the entire respiratory tree.

Results: FeNO at all flows resulted increased in both groups. However, patients with psoriatic arthritis have higher FeNO values to all flows, compared to psoriatic people ($P<0{,}001$). Likewise, both PASI and CASPAR exhibited a correlation with FeNO to all flows ($P<0{,}0001$).

Conclusion: Airway inflammation is higher in patients with psoriatic arthritis than patients with only psoriasis. Furthermore, PASI and CASPAR serve as a useful index to evaluate indirectly airway inflammation in patients with a negative spirometric test. Therefore, respiratory comorbidities need to be better detected with prospective studies.

Disclosure of Interest: None to declare.

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P141

12/15-Lipoxygenase products facilitate the generation of psoriasiform dermatitis in mice

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Introduction: 12/15-lipoxygenase (15-LO) is an enzyme, among others catalyzing the oxidation of membrane lipids as well as biosynthesizing a broad set of bioactive lipids. In general, 15-LO products can exert opposing pro- and anti-inflammatory net effects dependent on the detailed context of the inflammatory response. 15-LO products are also present in large quantities in lesional psoriatic skin, but their role in the pathogenesis of diseases is only poorly understood.

Objectives: We therefore investigated the role of 15-LO in psoriasis using the Aldara-induced psoriasiform dermatitis (AIPD) mouse model of the disease.

Methods: In these experiments, we compared the severity of skin inflammation in C57BL/6 wild-type and *Alox15*$^{-/-}$ mice. For this purpose, AIPD was induced by daily topical application of 50 mg Aldara cream for 5 consecutive days and clinical manifestation of the disease was evaluated based on a modified version of the Psoriasis Activity and Severity Disease Score (PASI), taking into account erythema, skin infiltration, and desquamation as criteria for the severity of skin inflammation.

Results: We have found that AIPD is attenuated in *Alox15*$^{-/-}$ mice in comparison to wild-type controls. Herein, erythema, skin infiltration, and desquamation are all reduced. Histologically typical signs of psoriasis, including keratinocyte hyperproliferation are less pronounced in *Alox15*$^{-/-}$ mice. Particularly epidermal hyperplasia, a signature feature of psoriasis, is significantly diluted in 15-LO-deficient mice indicating pro-proliferative actions of 15-LO products to the generation of full-blown AIPD. Additionally, chimera experiments with bone marrow reconstituted WT and Alox15$^{-/-}$ mice revealed an important role of 15-LO expression on hematopoietic cells for the development of full-blown AIPD.

Conclusions: Collectively, these results indicate that 15-LO actions may play an important role in the pathogenesis of psoriasis and highlight 15-LO as a promising pharmacological target in the treatment of the disease.

Disclosure of Interest: None to declare.

P142

A computational approach to identify new treatment options for psoriasis

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Introduction: Psoriasis with a prevalence of nearly 5% in North America calls for a more diverse treatment regimen. Current treatment options do not resolve the disease and have severe side effects.

Objectives: One approach to identify new therapeutics is the virtual screening of existing databases.

Methods: We here used the Connectivity Map (cMap) and publicly available microarray gene expression data of patient and mouse psoriatic skin to identify new treatment options for psoriasis.[1]

Results: With this method, we found 10 potential therapeutics. Some of these are already clinically used, whereas others are in phase 2 or 3 clinical trials. For most of the compounds an anti-inflammatory effect has not been yet described. To verify the *in vivo* efficacy of our results from the cMap, we have so far tested 6 of the 10 substances in the ALDARA-induced psoriasis-like skin inflammation dermatitis (AIPD) model in mice.[2] The drugs are applied either topically on the skin or given systemically via i.p. injection one day prior to ALDARA application. Scoring is based on the Psoriasis Area and Severity Index (PASI). Secondary endpoints are the epidermal thickness, the qualitative infiltrate of the epidermis and an increased spleen size and weight, which is a feature of this model. One of the tested drugs had a better therapeutic *in vivo* efficacy compared to corticosteroids, which reduced the disease score by 16%. Differences between the treatment groups became apparent on day 3. Compound 1 reduced the disease score by 34%. Mice treated with compound 1 also had a lower spleen weight compared to control.

Conclusions: Collectively, we here demonstrate the suitability of combining virtual drug screening with *in vivo* validation to identify new treatment options for psoriasis.

Disclosure of Interest: None to declare.

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P143

Epidermal Langerhans cells and dermal dendritic cells produce distinct and complementary cytokines that sustain the skin Inflammation in active psoriasis

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Introduction: Epidermis, the skin epithelia, consists of keratinocytes intermixed with Langerhans cells (LCs) and is separated from the underlying dermis containing dermal dendritic cells and vasculature. In psoriasis, red and scaly skin lesions are caused by vigorous keratinocyte activation and proliferation. We[1] and others[2] have shown that in active psoriasis, a high proportion of epidermal T cells produces the disease driving cytokines IL-17 and IL-22 whereas dermal T cells are more inert.

Objectives: In this study we aim to investigate if dendritic cells within the inflamed skin steer how epidermal T cells produce cytokines in psoriasis.

Methods: Skin biopsies were taken from healthy skin, psoriasis lesions and resolved skin after treatment (UVB or anti-TNF). Epidermal infiltrating DCs (iDCs) and LCs from epidermal skin suspensions were sorted for gene expression profiling or were stimulated with TLR ligands and analysed by flow cytometry.

Results: iDCs lacking Birnebeck's granules and langerin were identified in epidermis in addition to LCs in active psoriasis lesions by confocal imaging and electron microscopy. LCs were the main producers of the Th17 driving cytokine IL-23, measured both by RNA expression and flow cytometry, in comparison to iDCs. In contrast, epidermal iDCs produced IL-1β but also the regulatory cytokine IL-10. Epidermal LCs and iDCs from active psoriatic lesions could be stimulated to increase the production of the pro-inflammatory cytokines IL-1β and IL-23, whereas LCs from healthy skin remained inert.

Conclusions: Our results highlight the complexity of tissue inflammation in the skin and we show that infiltrating epidermal dendritic cells together with LCs may have the capacity to drive inflammatory T cell responses.

Disclosure of Interest: None to declare.

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Psoriasis screening qRT-PCR array as a potential tool for adjustment and monitoring the therapy of psoriasis patients

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Introduction: Psoriasis screening qRT-PCR array has been developed for monitoring of psoriasis patients undergoing isoflavone therapy. Genistein, a soy-derived isoflavone has attracted attention as a potent agent in treatment of psoriasis, as a mediator modulating expression of various genes, whose products are involved among others in different phases of the inflammation and proliferation.

Objective: In this study, mRNA expression profiling of genistein-treated human keratinocyte, healthy type and engineered skin psoriatic cells model was established in order to identify molecular markers for psoriasis, to find new potential targets for therapy and/or to develop a tool for treatment monitoring.

Methods: *In vitro,* two-dimensional (2D) engineered skin psoriatic cells model was developed by treatment of the HaCat cells either with a mix of proinflammatory cytokines: IL-1A, IL-17A, IL-22, OsM, TNFα and INF-γ, or by the growth of keratinocytes in a combined culture with monocytes. Gene expression profiling was performed by means of HumanHT-12 v4 Expression BeadChip and real-time qRT-PCR custom panel on keratinocytes treated with genistein, and mRNA levels were determined relative to those in untreated cells.

Results: Testing the effects of genistein on human keratinocyte transcriptome via the microarray analysis, we found that this compound induced significant dose- and time-dependent alterations in profiles of hundreds of transcripts. These changes included psoriasis-related genes. Modulation of their activities, by reducing the expression efficiency of genes revealing enhanced activity in psoriatic cells, and by stimulating the expression efficiency of genes revealing decreased activity in psoriatic cells was noted. Following confirmation of these results by qRT-PCR, chosen genes were utilized to design a psoriasis-screening qRT-PCR array panel, dedicated to the analyses of skin samples taken from psoriasis patients.

Conclusions: Our results suggest that aberrant expression of genes contributing to the progress of psoriasis can be improved by the action of genistein. This knowledge can be potentially used to monitor the molecular response of patients with psoriasis to treatment with genistein.

Disclosure of Interest: None to declare.